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1st prioritisation Report on survey design: Study protocols, SOPs and Guidelines, tailored and transferred questionnaires for recruitment and sampling

Deliverable Report

D 7.3

WP 7 - Survey design and fieldwork preparation

Deadline: January 2018

Upload of update v2.0 by Coordinator: 7 November 2018

Entity	Name of person responsible	Short name of institution	Received [Date]
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Additionally, the content of SOP on 'Sample Exchange on a pan-European level to be used in the HBM4EU initiative', produced within **Task 7.4**, led by Dominik Lermen (IBMT) is considered an important SOP to be taken into account like the SOPs attached to this deliverable, but can only be found attached to the deliverable of Task 7.4, D7.2.

Thanks to all partners of Task 7.2, 7.3 and 7.4 who supported this deliverable.

This document has been created for the HBM4EU project. HBM4EU has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733032.

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History of Changes

Version No.	Major changes
2.0	<ul style="list-style-type: none"> - revised basic questionnaire and corresponding interviewer manual (Annex 2.1.1 and 2.1.2) - revised SOP 3 (Annex 2.2.3) - added matrix-specific questionnaire and corresponding interviewer manual (Annex 2.1.3 and 2.1.4) - added Concept for the development of non-responder questionnaires in the scope of HBM4EU (Annex 2.1.5) - added satisfaction questionnaire (Annex 2.1.6) - changed text passages to address added annexes - added recommendations for conduct of a pilot study - updated Section 6.6 Data management, analysis and evaluation

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1 Summary

Deliverable 7.3 provides a short introduction to main points essential to consider for the development of a new HBM-study or if an existing study is to be aligned in the frame of HBM4EU. It focuses on work of Task 7.2 “Strategies for recruitment and sampling” including all issues of fieldwork and of Task 7.3 “Questionnaires development” straightened to the first nine prioritised substances/substance groups. Issues on data management, ethics and data protection and communication are only briefly touched as these issues are well developed in other Work Packages and deliverables.

In addition to the short introduction to main issues of study conduct provided within D7.3 several annexes are provided which explain in different degrees of detail the issues of recruitment, fieldwork and sampling. A first overview is presented in the Concept of a Study Protocol which provides basic information for planning a study. The Fieldwork Manual aims at offering detailed information on a study including blueprints of all documents. Here, a template is provided to be completed in the preliminary stages of each study. Also, the main fieldwork instrument, a basic questionnaire is provided accompanied by an Interviewer Manual explaining the background of each question. Documents providing even more details are the Standard Operating Procedures presented as templates for different issues of recruitment, fieldwork and sampling.

Developing a new – preferably representative – study is a complex, long lasting procedure in need of fundamental planning in a multitude of processes. To facilitate the planning process for recruitment, fieldwork and sampling a Concept for a Study Protocol was developed based on five Phases (Phase 0: Planning Phase; Phase 1: Preparatory Phase; Phase 2: Concretisation Phase; Phase 3: Starting Phase; Phase 4: Fieldwork Phase), each Phase being explained in detail in the concept. Following these phases will allow planning a study in a directed manner facilitating the planning.

Each (aligned) study will have to produce a tailor-made study protocol. This can easily be performed if the issues raised for decision in Phase 0, like type of study design, all aspects of biological samples and sampling, way of recruitment of participants and their involvement via questionnaires and providing samples and the way to assure the quality of all steps, are answered for each respective study. In the following Phase 1 documents have to be prepared. Subsequently, in Phase 2, material is to be bought and then the study can start with getting participant addresses and involving eligible participants in the fieldwork, accompanied by communication and quality control measures. When all fieldwork is finished and samples analysed data has to be checked and imported to the HBM4EU repository for further data analysis.

D7.3 and the Concept of a Study Protocol not only cover the general population but also give some input to occupational studies or to integrating occupational aspects into other studies, respectively.

Additionally dealing with already biobanked samples is addressed in the provided documents.

As mentioned above, other important aspects like ethics and data management are only roughly touched in this deliverable – here it is referred to the respective Work Packages.

Whether a new study is to be planned or if an existing study is to be aligned or perhaps biobanked samples are to be used in the frame of HBM4EU: Deliverable 7.3 and the accompanying documents build a powerful base to develop the necessary documents vital for a harmonisation of the studies and indispensable to develop European reference values.

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2 List of abbreviations

COPHES	Consortium to Perform Human Biomonitoring on a European Scale
DMP	Data Management Plan
EJP	European Joint Programme
EQUAS	External Quality Assurance Scheme
GDPR	General Data Protection Regulation
HBM	Human Biomonitoring
ICI	Interlaboratory Comparison Investigation
IPCHEM	Information Platform for Chemical Monitoring
QA/QC	Quality Assurance/Quality Control Scheme
QAU	Quality Assurance Unit
SOP	Standard Operating Procedure
WP	Work Package

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3 Introduction

Deliverable 7.3 (D7.3) is a joint work of Task 7.2 “Strategies for recruitment and sampling” and Task 7.3 “Questionnaires development”, and also connects to one SOP from Task 7.4 “Sample Exchange on a pan-European level to be used in the HBM4EU initiative” (to be found in D7.2) to complete the documents. Main aim of this deliverable is to provide all information necessary for recruitment, fieldwork and sampling of human samples for new HBM-studies or studies to be aligned in the frame of HBM4EU; be it for the general population or for occupational subgroups. In addition, it covers existing (biobanked) samples to fill identified data gaps for the development of European reference values.

D7.3 introduces essential issues necessary for a proper study conduct (see Chapter 0) more detailed described in the documents of the Annex (Concept for a Study Protocol, Fieldwork Manual, Standard Operating Procedures (SOPs) for selected issues, different questionnaires together with an Interviewer Manual). Taking into account that it is impossible to provide one Study Protocol that suits all situations and that decisions on studies to be aligned or newly build up have not been taken in the first ten month of the project, Task 7.2 and 7.3 decided to provide general and not study-specific documents which need to be adapted to the selected studies in 2018.

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4 Background

Main aim of the HBM4EU EJP is to collect data on the body burden of European citizens to prioritised harmful substances to consult policy actions.

The HBM4EU EJP builds on previous and ongoing EU initiatives, national HBM programmes and studies. To this end, existing data gaps can be closed by three different measures (see Figure 1):

Use of biobanked samples,
Alignment of ongoing studies,
Conducting new studies.

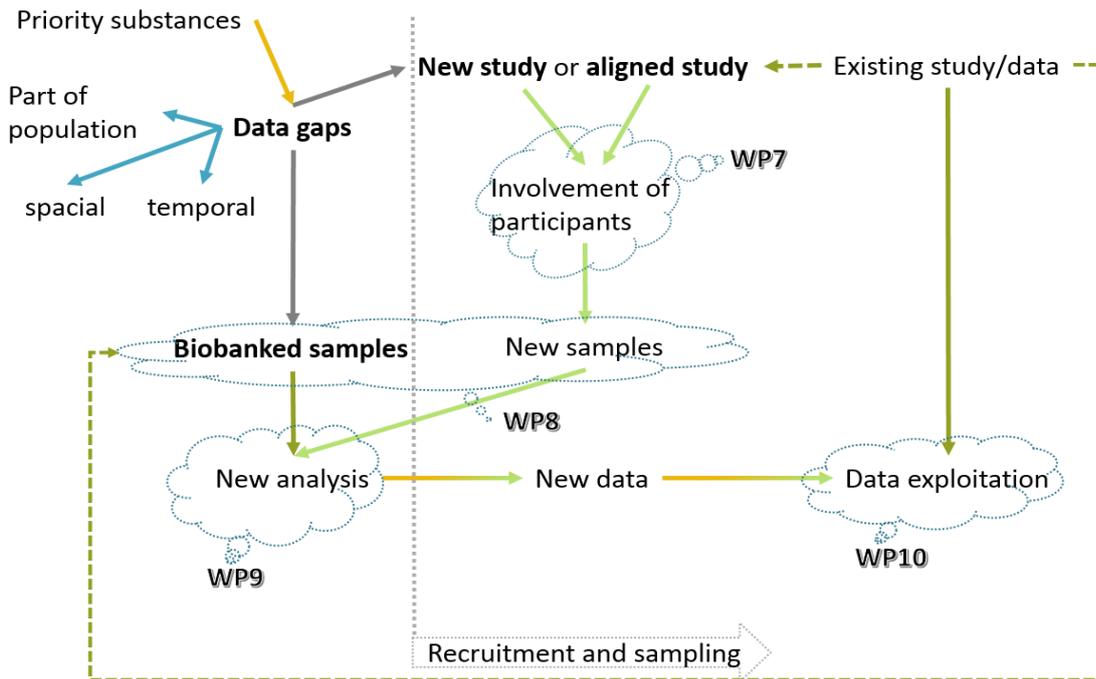


Figure 1: Overall strategy to fill the identified data gaps

A fourth possibility is to exploit existing data which is the responsibility of WP 10. WP 7 mainly deals with the involvement of participants and provides guidelines for a proper study conduct or approach to biobanked samples. Whereas WP 8 is responsible for conducting new or aligning ongoing studies, and use of existing samples (using documents produced within WP 7) and WP 9 deals with analyses of collected human samples.

To obtain comparable European data a harmonisation of data collection procedures is essential. Task 7.2 and Task 7.3 provide with this deliverable guidelines and templates for a harmonised data collection for 1st priority substances for partners of HBM4EU to produce data that can be uploaded to IPCHEM to be used to derive European reference values.

Task 7.2 aims at providing guidelines for cost effective study designs to fill identified data gaps. The most cost effective way to obtain new data is to use biobanked samples. No participant recruitment or fieldwork is required which usually is costly and time consuming. A prerequisite to be able to use biobanked samples in the frame of HBM4EU is their availability for HBM4EU, existing or available ethics and data transfer documents, correctness of preanalytical processes and materials, and information on the sampling and storage conditions and availability of corresponding questionnaire data. Alongside these technical prerequisites the samples have to be comparable in regard to target population group, inclusion or exclusion criteria and representativeness (see also Figure 2).

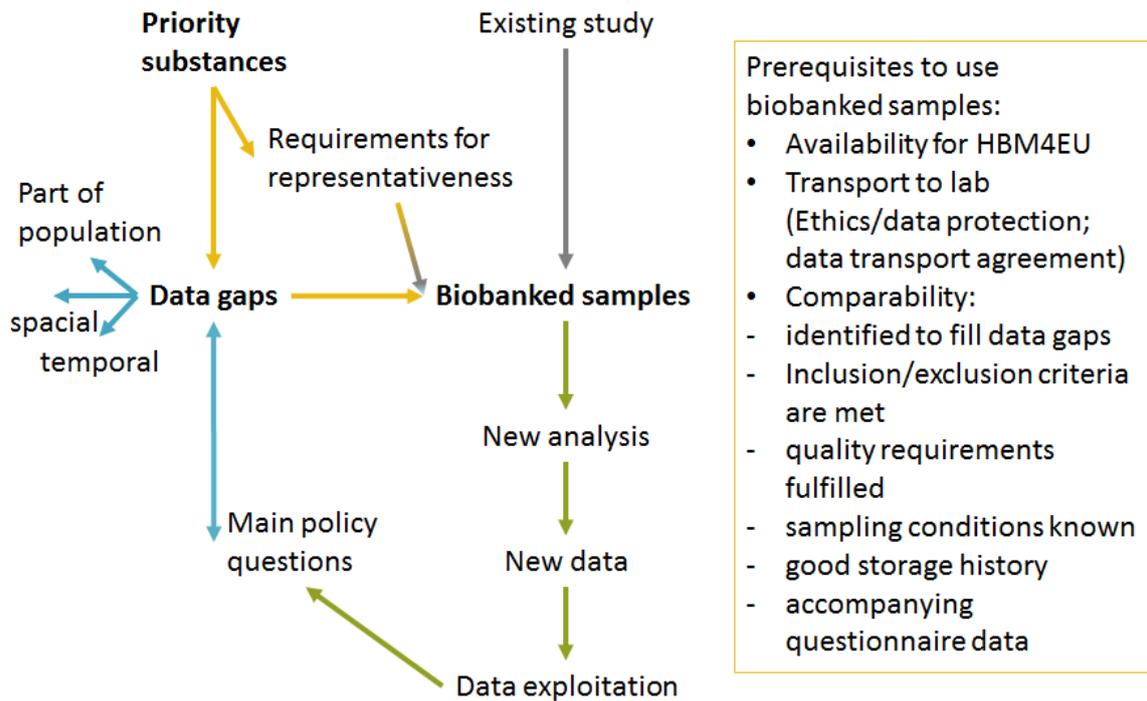


Figure 2: Overall strategy to fill the identified data gaps by using biobanked samples

Exchange of biobanked samples has to be prepared properly – more information on these issues is provided by Task 7.4, deliverable D7.2 and in the respective SOP in the attachment of D7.2.

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Main focus of this deliverable is on recruitment, fieldwork and questionnaires which are needed for new studies or studies to be aligned in the frame of HBM4EU. An overview of the general strategy for aligned or entirely new studies is provided in Figure 3 and will be explained in the course of this deliverable.

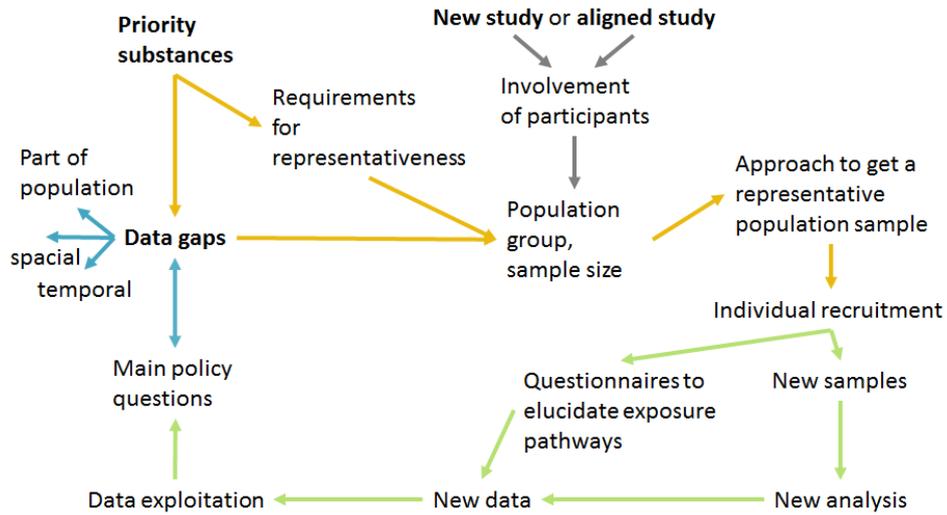


Figure 3: Overall strategy for recruitment and sampling for new or aligned studies to fill the identified data gaps

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5 Phases Concept for the Study Protocol

Main instrument to plan a study is the Study Protocol which informs about each necessary step for a proper study conduct. Initially it was planned to provide several tailored study protocols that fit to the different studies which will be aligned or initiated in the frame of HBM4EU to close identified data gaps. But actually it is not possible to provide one Study Protocol that suits all situations. Additionally, decisions which studies shall be aligned or newly build up for HBM4EU purposes took longer than expected and have not been taken in the first ten months of the project. Therefore, a Concept for a Study Protocol and SOPs and a general questionnaire which need to be adapted to the selected studies in 2018 have been developed for this deliverable.

Usually a Study Protocol involves many tasks which have to be organised – a lot of them in parallel. The Concept for a Study Protocol provided in the Annex is a template or model for a general study protocol for human biomonitoring (HBM) studies to be conducted in the frame of HBM4EU. To facilitate the planning of a study a concept was developed which focuses on different phases of the study development, providing a good overview on all necessary steps. This can help keeping track of schedule and key players.

The idea of the Phases Concept is to split up a study into different phases as for each study decisions in different fields have to be taken. Most tasks for a study have to be prepared in advance, and, before the real study can start, preparations have to be made operational, e. g. material has to be bought. Participants have to be recruited and involved when they meet the inclusion criteria and only then the fieldwork can start, i.e. participants are involved through questionnaires and providing samples. All this is explained in the different Phases. Figure 4 gives an overview of possible phases of a (HBM) study and their characteristics to enable a smooth organisation of a new study. Actually some issues of single Phases may partly overlap.

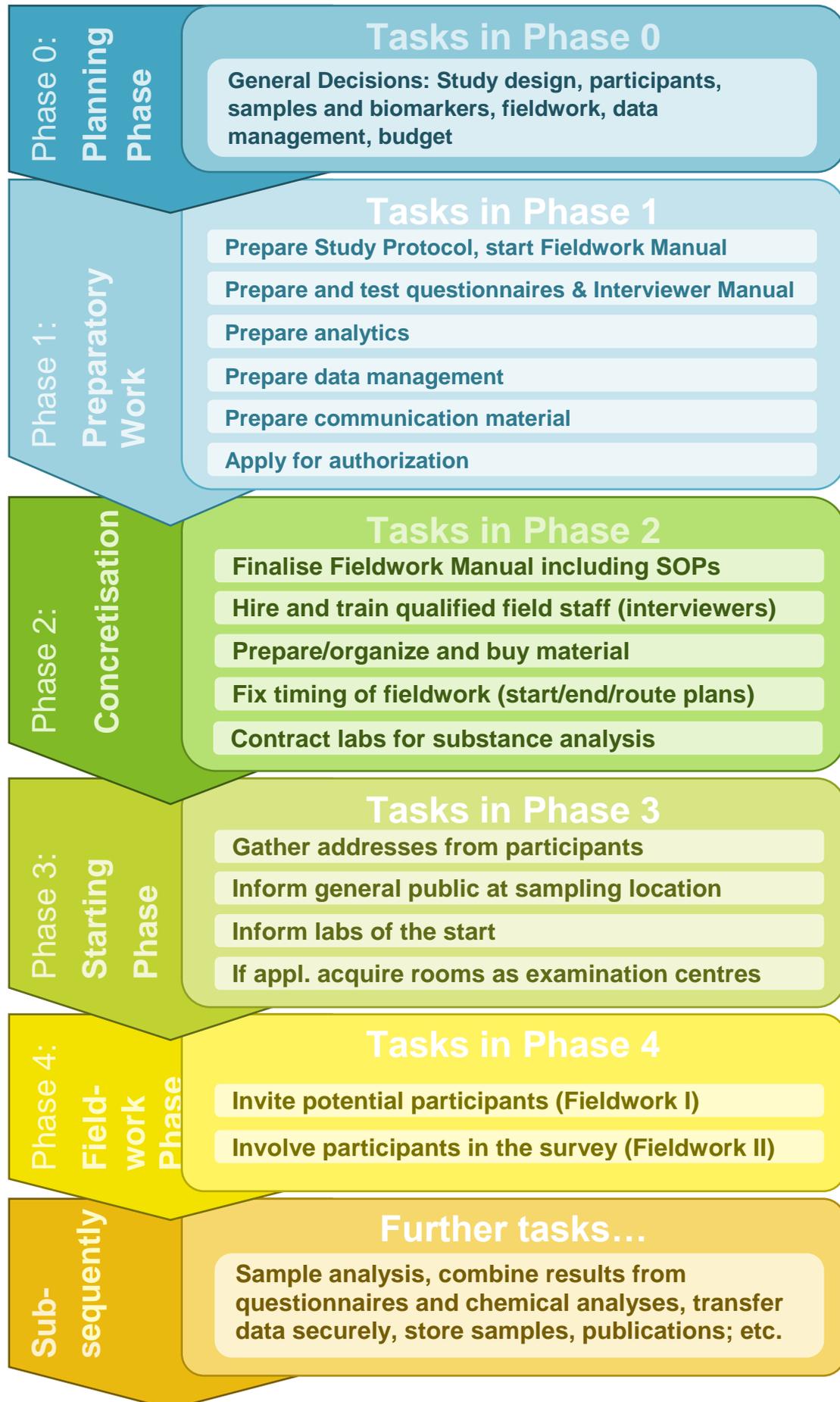


Figure 4: Phases of a study and its characteristics in general

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Figure 4 merely provides a rough overview of the Phases including only questionnaires, urine or blood sampling. It is also possible to integrate more instruments e.g. sampling of drinking water. These additional instruments have to be considered in each of the phases accordingly. A more detailed overview table and description of the phases is provided in the Study Protocol (Annex 1). This Study Protocol also describes Phases for using biobanked samples or for aligned studies separately.

Within this Phases Concept the regular parts of a study protocol (Study design, selection of participants, recruitment, biological samples, fieldwork and analysis) are addressed as well (see Figure 4). Table 1 provides an overview on issues which need decisions in Phase 0, the Planning Phase. Each single part is described in detail in the Study Protocol in Annex 1.

Table 1: Topics to be decided on in Phase 0 of a study

1. Study design	<ul style="list-style-type: none"> • Aim for representativeness (sample size) • Type (cohort, case control, cross-sectional?) • Timing, Duration, Follow up? • Ethics and data protection • Data management
2. Selection of participants	<ul style="list-style-type: none"> • Target population • Sampling frame • Region • Inclusion/exclusion criteria
3. Recruitment and Fieldwork I (individual recruitment)	<ul style="list-style-type: none"> • Communication • Approach to address holder • Method and frequency to approach participants
4. Fieldwork II (investigation of participants)	<ul style="list-style-type: none"> • Instruments to be applied (Questionnaires, Samples (blood, urine, indoor air, drinking water, etc.)) • Place of direct contact to participants • Questionnaire(s) application • Sample collection and further processing • Incentives
5. Analytics	<ul style="list-style-type: none"> • Substances • Matrices • Volume • Biobanking

HBM4EU builds on experiences from former projects, like COPHES. The COPHES Deliverable 2.2¹ “Adapted general guidelines for study design and selection of the participants, recruitment and sampling, quality control measures concerning fieldwork and adapt questionnaire to be the basic

¹See also: Becker, K., M. Seiwert, L. Casteleyn, R. Joas, A. Joas, P. Biot, D. Aerts, A. Castano, M. Esteban, J. Angerer, H. M. Koch, G. Schoeters, E. Den Hond, O. Sepai, K. Exley, L. E. Knudsen, M. Horvat, L. Bloemen, M. Kolossa-Gehring and D. consortium (2014). "A systematic approach for designing a HBM pilot study for Europe." *Int J Hyg Environ Health* **217**(2-3): 312-322. and Fiddicke, U., K. Becker, G. Schwedler, M. Seiwert, R. Joas, A. Joas, P. Biot, D. Aerts, L. Casteleyn, B. Dumez, A. Castano, M. Esteban, J. Angerer, H. M. Koch, G. Schoeters, E. Den Hond, O. Sepai, K. Exley, L. E. Knudsen, M. Horvat, L. Bloemen, A. Katsonouri, A. Hadjipanayis, M. Cerna, A. Krskova, J. F. Jensen, J. K. Nielsen, P. Rudnai, S. Kozepesy, A. C. Gutleb, M. E. Fischer, D. Ligocka, J. Kaminska, M. F. Reis, S. Namorado, I. R. Lupsa, A. E. Gurzau, K. Halzlova, D. Mazej, J. S. Tratnik, T. C. Rivas, S. Gomez, M. Berglund, K. Larsson, A. Lehmann, P. Crettaz, M. C. Dewolf, D. Burns, A. Kellegher and M. Kolossa-Gehring (2015). "Lessons learnt on recruitment and fieldwork from a pilot European human biomonitoring survey." *Environ Res* **141**: 15-23.

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module for MS questionnaires” (2011) is available by its co-author (U. Fiddicke). The COPHES Deliverable 2.2 describes in detail alternative approaches to the main topics addressed in Table 1 and their advantages and disadvantages, therefore this was not repeated for HBM4EU. Becker, et al. (2014) describe very well the systematic approach developed in this COPHES deliverable. COPHES Deliverable 2.2 also gives examples for Standard Operating Procedures (SOPs) for e.g. *“Selection of Participants”* and *“Recruitment and Fieldwork”* designed to be applied for DEMOCOPHES with some flexibility but not requiring population representativeness on country level. DEMOCOPHES was a pilot HBM-study on children and their mothers running in parallel in 17 European countries, analysing 4 substances and some metabolites. In contrast to the COPHES/DEMOCOPHES documents, the Study Protocol provided herewith focuses on those alternatives which will lead to representative data/ random selection to be used in the frame of HBM4EU and can be used as a template for different population groups.

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6 Management of the Study at national level

Responsibility: Each country willing to participate in the HBM4EU project will be responsible for all aspects of study conduct on the national level. HBM4EU provides templates and recommendations which should be followed as close as manageable as a prerequisite for merging all European data to derive European reference values. Most important aspects to be followed by each country are on one hand those which directly influence the representativeness of the selected study population. On the other hand quality assurance aspects are of utmost importance. Quality assurance is widely respected for analytical procedures within the labs but has to be considered for all other parts of the study, too. An important instrument for quality assurance is the training of involved personnel (partly provided by HBM4EU) and the provision of a Fieldwork Manual (see Annex 2).

Translation: The templates for the Study Protocol, SOPs, the Fieldwork Manual and the questionnaires are provided in English but reflect experiences of different parts of Europe. To be ready to use in the countries each country has to translate the documents into national documents. This translation touches not only on the language(s) but also on specific national features which may not have been regarded in the templates. Additionally, national ethic and data protection issues have to be considered as they may be different in the countries. It is important that all deviations from the provided templates are documented with the data to be available when it comes to data analysis and interpretation. The translated documents must be tested before being made operational. This means that a small-scale validation exercise has to be performed with the questionnaires and if possible a pilot study should be planned and conducted before the start of a new study.

Concept: An easy way to develop a concept for a HBM-Study is to follow the structure of the attached Concept for a Study Protocol, respecting all decisions which have to be taken for a proper study conduct. As mentioned above the focus lies on recommendations which lead to a representative population sample – or at least a sample collected randomly which enables the transfer of the results into European reference values. The main parts of a study – study design, selection of participants, recruitment and fieldwork (including specimen sampling) and analysis are shortly introduced below. Ethics, data management and communication aspects are additionally slightly touched even though they are elaborated in detail in other Work Packages and deliverables.

6.1 Study design

In 2011 the pilot study DEMOCOPHES tested the feasibility of a pan-European HBM programme using a cross-sectional study design and collecting specimen from 120 mother-child-pairs in 17 European countries (Joas, Casteleyn et al. 2012, Den Hond, Govarts et al. 2015).

The cross-sectional study design only allows for a snapshot of the current disease prevalence in relation to current exposure (Goldberg, McManus et al. 2013), but may still provide information on the effectiveness of bans and measures to reduce the use of certain chemicals. This is one reason why many of the countries participating in HBM4EU that gathered previous experience with HBM-surveys have been using the cross-sectional study design for their national surveys. The publications listed in the following are an example for the variety of HBM studies performed in different countries within the consortium: Austria (Hohenblum, Steinbichl et al. 2012), Belgium (Reynders, Colles et al. 2016), Czech Republic (Cerna, Krskova et al. 2012), France (Frery, Vandentorren et al. 2012, Dereumeaux, Fillol et al. 2016), Germany (Schulz, Conrad et al. 2007), Italy (Bocca, Mattei et al. 2010) and Spain (Pérez-Gómez, Pastor-Barriuso et al. 2013).

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It is concluded that many of the countries participating in HBM4EU are familiar with the cross-sectional study design. In combination with its characteristics to be easier and cheaper to conduct and the timeframe of HBM4EU make the cross-sectional study design the most likely to be used within the HBM4EU programme.

Therefore, the recommended choice for new studies in the frame of HBM4EU would be cross-sectional surveys. They serve in filling knowledge gaps, support organising harmonised EU-wide HBM studies and can provide scientifically backed answers for policy questions. Cross-sectional surveys can be repeated within the same subjects, thus including the option of a longitudinal exposure assessment to assess temporal trends in exposure, or if prospective in terms of follow-up of the outcome to establish temporal ordering between exposure and health outcome. Single countries can add particular extensions to fill certain gaps.

In order to provide policy-makers and the general public with science-based knowledge on validated chemical exposure data and information on associated health impacts at EU level as set out in the HBM4EU programme, one type of study design alone may not be sufficient. For example, when the exposure in relation to a certain health outcome is of interest, well-designed case-control studies could be set up. Table 2 provides an overview of selected study designs. The feasibility of developing new studies with other investigative study types in HBM4EU will have to be carefully considered throughout the project.

Biobanked samples can be taken from different kind of studies, cross-sectional studies, cohorts or case-control studies (just to mention the main study types). The same accounts for studies to be aligned.

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Table 2: Overview of selected study designs

Alternatives	Advantages	Disadvantages	Issues to consider
Cross-sectional study	Provides snapshot of disease prevalence/effect biomarker in relation to exposure at a given time point	Cannot prove causation, no temporal ordering between health outcome and exposure possible	Experience available in several European countries. Can be representative
Case-control study	Can establish a connection between specific health effects and a certain exposure, possible to study rare outcomes	Health outcome has to be decided beforehand, only one health outcome at a time can be studied	Not representative, but could be a surplus in the HBM4EU section focusing on exposure and health relations. HBM4EU partners have experience with case-control study design
Cohort study	Temporal ordering between health outcome and exposure, can be designed to study rare exposures	Expensive and time-consuming	Several HBM4EU partners have experience with cohort studies
Cross-sectional study including option of a longitudinal follow-up of both exposure and outcome	Combines the advantages of cross-sectional and cohort studies	Expensive and time-consuming. Can be difficult to establish	Allows for generating results during the project and (optionally) afterwards which would promote sustainability in the participating countries. Follow-up using health registers is possible among some of the HBM4EU partners

6.2 Selection of participants, inclusion and exclusion criteria, geographical distribution

A multistage probability sampling method among the participating EU countries was suggested as the ideal selection protocol, as described in the updated Deliverable 8.1 which includes a report on the proposal for a representative sampling strategy on EU level –being available on the HBM4EU webpage. Each participating country in HBM4EU is a primary sampling unit (PSU). To attain an entire European coverage within HBM4EU, a European maximal scenario would be sampling in each of the participating EU countries. To ensure sampling feasibility and due to financial constraints, the number was reduced to 12-15 European countries. These countries need to be distributed over all geographical regions in Europe. Four geographical regions (clusters) are defined according to the United Nations geoscheme for Europe (https://en.wikipedia.org/wiki/United_Nations_geoscheme_for_Europe): Northern Europe, Eastern Europe, Southern Europe and Western Europe.

Within HBM4EU the participating countries are attributed to the four different geographical regions as follows: Northern Europe: Denmark, Finland, Iceland, Ireland, Latvia, Lithuania, Norway, Sweden, United Kingdom; Eastern Europe: Czech Republic, Poland, Slovakia; Southern Europe:

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Croatia, Cyprus, Greece, Italy, Portugal, Slovenia, Spain; Western Europe: Austria, Belgium, France, Germany, The Netherlands, Switzerland.

The sampling domains for which at least specified reliability is desired in Europe are **gender** and **age** groups. The seven age groups that are targeted within the HBM4EU surveys are: 0-2y, 3-5y, 6-11y, 12-19y, 20-39y, 40-59y, 60-79y.

In each participating country, and for each of the selected age groups **150 male and 150 female participants** recruited from the **general population** (i.e. non-hospitalised individuals) are included. The sample size was chosen to ensure also inclusion of participants from different socio-economic strata and from different community sizes (urban, suburban, rural). To include different socio-economic classes, education level can be used as a proxy (International Standard Classification of Education (ISCED), which includes 9 levels of education (ISCED 2011, see task 7.2 report). The sample size is indicative and may need further adjustment for the specific chemical group because of expected population variability of the biomarker. The way of recruiting the participants (via schools, work, registries) is not prescribed within HBM4EU. However, a good sampling frame model for selection of individuals is the stratified clustered multi-stage design. Via this design, geographical areas (stratification) are selected within a country. Within each of the geographical areas, primary sampling units (PSU: schools, work registries, general practitioners) are selected randomly, however that can be done in a way that there is an increased selection chance proportional to the number of individuals in these PSU. Furthermore, individuals are selected randomly within the PSU.

Considering the geographical locations, **inhabitants from urban, suburban and rural areas are accepted. Hot spot areas, with known historical/actual environmental contamination need to be excluded.**

No further inclusion and exclusion criteria are set. However, the following minimal information needs to be collected (e.g. in the basic questionnaire), to have an indication of the population included:

- ▶ Life style: information on smoking and alcohol/drugs use, type of diet, housing conditions, hobbies and occupational exposure
- ▶ Socio-economic status needs to be documented (using ISCED education levels)
- ▶ Residential history: number of years living in the country
- ▶ Geographical coverage: urban/sub-urban/rural
- ▶ Sampling time period needs to be reported (no seasonal restrictions are set).

The way of recruiting the participants (via schools, work, registries) is not prescribed. No restrictions are set.

6.3 Recruitment, Fieldwork I and II, and quality assurance

Procedures for recruitment and fieldwork depend mainly on the target population and the instruments to be applied in the study. Recruitment covers all issues of getting addresses of potential participants, therefore target population (age group), geographical region and sampling frame have already been decided upon. Institutions that can provide addresses of potential participants, e.g. population registries, maternities, schools (or school authorities) have to be contacted, informed about the study and asked for their support to enable a random sampling of potential participants. The approach to the institutions has to be prepared properly and accompanied by a communication strategy.

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A communication strategy is also important when it comes to Fieldwork I, which involves the contact to individuals (using either directly addresses of potential participants or addresses of institutions like schools or maternity care clinics where participants can be approached individually). Only when a “potential participant” actually agrees to be involved in the study and to participate to all necessary procedures and fulfils the inclusion criteria he/she becomes a “participant”. All approaches to potential participants until included in the study have to be documented and – most important – whenever possible at least some information should be obtained also from those potential participants who don’t agree to be involved in the study (non-responder analysis to evaluate if these systematically deviate from actual participants). The involvement of participants in the study, e.g. with answering questionnaires and providing samples, is covered by Fieldwork II (see Chapters 6.4 and 6.5).

Information on the study has to clearly specify the goals and the limitations, what is expected from the participants, how they can contribute, possible follow-ups, when and how the results will be communicated and interpreted. It has to be directed not only to potential participants but also to the providers of participant addresses and to the wider public (see Chapter 6.7 Communication).

The attached Study Protocol provides some general recommendations for different target groups which need to be adapted to the study that shall be conducted. These recommendations are based on expert input and upon experiences from European studies like DEMOCOPHES. They also take into account results from the questionnaire of Task 7.1 which asked the National Hubs, amongst other topics, about the way of national study conduct to base the recommendations also on feasibility and practicability in the majority of the HBM4EU countries.

An analysis of this questionnaire to the National Hubs (Task 7.1) revealed that in the majority of the countries participants for national or regional representative studies were approached via different kind of registers (e.g. population registers), if suitable for the targeted population group. Other approaches were direct contacts to potential participants, e.g. mothers or workers or pupils which more easily could be reached by direct contact through the institutions. One should bear in mind that direct contact can only lead to representative samples if the premises (maternities, schools) to be approached were selected randomly and with regard to statistical procedures. The same also applies to the selection of potential participants

Another result of the analysis of the 7.1-questionnaire was that the recruitment contact was mostly done via telephone or mailing whereas emails and internet contacts were just rarely used (in 1 of 15 countries for national representative studies and 4 of 21 countries for regional representative studies). All except two countries used a Face-to-Face interview as the mode of data collection but additionally most countries (also) used self-administered questionnaires (preferably on paper, some online versions).

For the location of the examination the countries reporting to have national or regional representative studies used either the homes of the participants or examination centres. Mobile labs were only used in two countries for selected studies. If mothers or patients were the target population hospitals or maternities were also used for the interviews.

The attached Study Protocol leads step by step (phase by phase) through the decisions to be taken for a proper study conduct regarding recruitment and fieldwork I and II. It also stresses the importance of quality assurance as it is in the interest of all partners involved that the fieldwork is done properly. Quality assurance starts right at the beginning with the selection of participants. The aim of conducting a study in the frame of HBM4EU is to enable a transfer of study results to the intended target population. Therefore the selection should be appropriate for representative sampling, recommended options should safeguard avoiding a selection bias. For this reason the

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Study Protocol e.g. does not consider convenient sampling e.g. sampling of volunteers after public call in the media.

Quality assurance is also important for all following steps of recruitment and fieldwork. As stated above during the recruitment process, it is not only important to get information on participants but also on non-participants. Also fieldwork needs to be controlled and checked. Systematic or unsystematic errors might slip in over time and be covered by routine-blindness. A Fieldwork Manual (see Annex 2) provides a good basis for quality assurance and control. It keeps a copy of all documents for the participants and explanations on all procedures. Checklists including all important steps of the procedures are to be used. Additional quality control measures are field visits by supervisors from the field team and from external experts. These are recommended for each study. Apart from the Fieldwork Manual a central element of quality assurance is the training of the interviewers not only at the beginning of a study but also during the study's conduct. Providing an Interviewer Manual with background information on the questions and on the way of questioning also supports high quality (see Chapter 6.4.2).

6.4 Collection of Information

Human biomonitoring studies require collecting information from participants as it allows a proper interpretation of the exposure levels. Thus, several questionnaires (listed below) have been elaborated under the HBM4EU framework to gather harmonised information from the population selected to participate in this study. Likewise, other relevant information on the data collection process regarding HBM4EU is also detailed hereinafter.

6.4.1 Questionnaires

Task of Task 7.3 is the development of questionnaires with the aim of collecting information from each participant in a standardised way as this will enable to obtain comparable results across countries involved in the HBM4EU study. Below different types of questionnaires developed to be used in the frame of HBM4EU are described shortly. All questionnaires are to be found in Annex 2.1.

6.4.1.1 Basic questionnaire

The basic questionnaire has been designed to collect all the necessary information concerning individual characteristics of the participants and different exposure pathways with special focus to characterise as well as possible the level of exposure to the 1st-priority substances selected for study. It is provided in Annex 2.1.1.

To safeguard that this questionnaire is based on existing experience and knowledge first a checklist was elaborated to identify groups or blocks of questions worth being included in the questionnaire. After discussions in Task 7.3 major topics were identified: I) sociodemographic characteristics; II) exposures to a range of compounds in the residential environment; III) dietary habits; IV) lifestyles; V) occupational exposures; VI) health status. Additionally an online systematic search was conducted to identify questionnaires already used in relevant human biomonitoring studies carried out in other countries around the world Canada, Czech Republic, Denmark, France Germany, Italy, Israel, Korea, Russia, Spain and USA, as well as countries participating in the DEMOCOPHES project. Questionnaires identified were evaluated using an evaluation sheet, based on an extension of the previous checklist to identify relevant questions that should be included in the basic questionnaire.

The resulting basic questionnaire takes into consideration questions identified through the evaluation of questionnaires and other questions proposed by partners according to their relevance

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for the study covering the first priority substances, providing information on socio-demographic characteristics, residential environment and home exposures, dietary habits, lifestyle, occupational exposures and health.

The information provided by this questionnaire will be essential for the statistical analysis of the results derived from the study since it allows the identification of the major variables related with exposure to those compounds under research.

With this procedure the basic questionnaire is based on experiences of other epidemiological studies. Not included in the scope of Task 7.3 was to validate the basic questionnaire or to test its feasibility in a small group of volunteers. A feasibility test is part of a pilot phase before each study.

6.4.1.2 Specific questionnaires on 1st-priority substances

HBM4EU defined a list of 1st-priority substances to be studied: Phthalates/DINCH, Bisphenols, Per-/Polyfluorinated compounds, Flame Retardants, Cd, Cr, and PAHs and Anilin family: MOCA. Hence, specific questions on these compounds were elaborated by partners according to their expertise, which were further incorporated into sections of the basic questionnaire, as appropriate. The purpose of these questions is to account for specific sources and routes of exposure to these priority substances, which will assist the interpretation of the results derived from the study. Specific questions just addressing single substances/substance groups have been highlighted in a modified version of the basic questionnaire (provided in Annex 2.1.1) in order to be identified.

6.4.1.3 Sampling questionnaires/matrix-specific questionnaires

A sampling questionnaire/matrix-specific questionnaire, specific for each biological matrix, was elaborated in early 2018 to collect relevant information on the conditions in which biological samples are collected (e.g. time, date, fasting period, among others). These questionnaires are necessary for a proper interpretation of biomonitoring data.

The annex to this deliverable includes the matrix-specific questionnaires for the sampling of urine and blood as well as the corresponding interviewer manual for the 1st-priority substances (Annex 2.1.3 and Annex 2.1.4 respectively).

6.4.1.4 Non-responder and satisfaction questionnaires

A non-responder questionnaire and a satisfaction questionnaire shall also be administered to the target population of the study. The first one will allow identification of potential differences between people participating and those who are not participating in the study, in order to identify a potential selection, affecting the generalisability. The satisfaction questionnaire will be used to assess the view of the participants concerning the conduct of the study and the processes of collecting information and samples which could help to improve further studies.

A concept for the development of non-responder questionnaire in the scope of HBM4EU was developed and can be found in Annex 2.1.5 to this deliverable. Annex 2.1.6 contains the satisfaction questionnaire.

6.4.2 Application of questionnaires, Interviewer Manual

A personal interview is the method most commonly used to collect information from chemical exposures. However, this method tends to underestimate certain exposures (for example smoking) and socially undesirable behaviours can be underreported as well, the so called 'social desirability' bias. Nonetheless, interviews have the advantage of reducing misunderstanding of some questions, thus optimising data quality.

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The developed HBM4EU questionnaires have been designed to be administered to study participants by trained interviewers with pencil-and-paper. Hence, both, questions and alternative responses have been elaborated to be read by interviewers, who will also mark the corresponding responses in the questionnaire. However, Computer-Assisted Personal Interviewing (CAPI) can be developed in the countries based on the provided paper version. It is envisaged that (web-based) Computer-Assisted Self Interviewing (CASI) will not be used to collect information, this would need special adaptations.

Training of interviewers (and their assistants) is essential to perform the interviews in a standardised way. The training of interviewers has been shown to improve their performance, particularly by increasing the response rate and by reducing under-reporting of information or the rate of non-response to particular items. Training of interviewers may be provided within HBM4EU and an instruction manual for interviewers (Interviewer Manual, see Annex 2.1.2) designed specifically for HBM4EU will be introduced, which will include guidelines for the application of the questionnaires in order to improve the collection of relevant information for the study. An overarching HBM4EU training does not replace individual trainings on selected studies in the countries.

6.4.3 Adaption of questionnaires for aligned studies

The questionnaires mentioned above can be adapted for further use in occupational or health studies, among other aligned studies. When surveys involving specific chemical substances or addressing specific matters (e.g. health) are planned, questions related to these points can be obtained from the basic questionnaire, as the objective and background of each question is well-identified in the Interviewer Manual.

6.5 Biological samples and analytics

Human biomonitoring is a valuable tool for the prevention of human health problems, the monitoring of the effectiveness of the environmental and health policies or to follow temporal trends. After decisions on the substances to be focused on are taken, decisions on the biomarker, the kind of sample (urine, or blood etc.), the volume or amount necessary follow closely. Additionally, it has to be decided how, when and by whom the samples will be collected, further processed and transported to the analysing lab, and about the materials used for these procedures.

6.5.1 Pre-analytical and analytical phases

To exploit the potential of human biomonitoring it is necessary to ensure the quality and comparability of the analytical results. To achieve this aim, in HBM4EU it has been designed a complete Quality Assurance/Quality Control Scheme (QA/QC) that will cover the analytical phase as well as the pre-analytical one.

The control of the pre-analytical phase includes the training of the fieldworkers and the use of Standard Operating Procedures (SOPs) describing the amount/volume/size of the sample(s) needed, the participant condition at the time of the sample collection and basic information related to the collected sample, the proper storage of samples until processing and analysis, shipment conditions, sample processing (centrifugation, timing, additives, etc.) and the procedure for partition / aliquoting. In all countries taking over the responsibility to conduct a HBM4EU study samples will be collected to be analysed, i.a. for the 1st priority substances. The sample collection has to follow SOPs which are provided in this deliverable, Annex 2.2.3 and the Study Protocol (see Annex 1) provides an overview on the timing of necessary planning of actions concerning sampling.

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For the control of the analytical phase a QA/QC scheme has been designed that will cover all the selected substances in the different prioritisation rounds. As it is described in the deliverable “D 9.4: *The Quality Assurance/Quality Control Scheme in HBM4EU project*”, the QA/QC scheme will involve at least three rounds of Interlaboratory Comparison Investigations (ICIs) and External Quality Assurance Schemes (EQUAS) (i.e. one ICI and two EQUAS or, two ICIs and one EQUAS). These exercises will be coordinated under Task 9.4 with the support of the Quality Assurance Unit (QAU) and the laboratories selected according to the list of candidate laboratories (see deliverable “D 9.3. *Databases of candidate laboratories for the 1st prioritisation round of substances*”). They could be considered as a training practice since they will be a possibility to check and improve the analytical method.

The aim of the ICIs is to measure the comparability (the degree of variation in analytical results) of participating laboratories. The consensus value, calculated as the mean of the results of the participants after exclusion of the outliers is used as reference. EQUAS are used to improve the accuracy (the ability to quantify the actual analyte concentration in the sample) of analytical results. Reference Laboratories are involved to derive assigned values as approximations of the true values and the results from participating laboratories are evaluated by comparing results with the assigned values.

A more detailed explanation about the design of the HBM4EU QA/QC Scheme, practical implementation and evaluation of the results can be found in the deliverable “D 9.4: *The Quality Assurance/Quality Control Scheme in HBM4EU project*”.

Only those laboratories obtaining successful results in the ICI/EQUAS exercises will take part in the analytical phase within HBM4EU.

6.5.2 Post analytical phase

The post analytical phase deals with e.g. storage requirements if it is planned to store samples in a biobank. An SOP also addressing storage and transport activities is provided by Task 7.4 “*Standard operating procedure for Sample Exchange on a pan-European level to be used in the HBM4EU initiative*” (see D7.2, Annex 1).

6.6 Data management, analysis and evaluation

Data management is an important part of each study which needs thorough reflection. Detailed information on HBM4EU data management (and links to download documents and templates mentioned below) is available at <https://www.hbm4eu.eu/data-management/>. In order to ensure that HBM4EU respects all relevant ethics and legal requirements at both national and European level, Task 10.1 has developed a Data Management Plan (DMP) and a Data Policy.

The Data Management Plan describes the data management life cycle for all datasets collected, processed as well as generated under the project. The Data Policy sets and describes the rules and procedures to ensure that data on human subjects are transferred and used in a secure setting, in compliance with ethico-legal requirements.

When possible, it is preferred that data are anonymised before exchange within HBM4EU. When anonymisation is detrimental to the study and/or to answer the research question, the established procedures to exchange non-anonymised data, i.e. personal data, shall be followed. To reduce the risk of re-identification, it is requested that such data are at least pseudonymised² before

² Pseudonymisation means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.

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exchange. Different legal restrictions apply to the exchange and use of anonymised versus non-anonymised data. The GDPR (general data protection regulation (Regulation (EU) 2016/679)³ applies for the exchange and use of personal data. Anonymised data are not considered personal data, while non-anonymised (including pseudonymised) data are. Hence, the HBM4EU data policy discriminates between the sharing of anonymised and pseudonymised data.

Table 3 provides a pre-checked table with the minimal requirements for sharing of HBM4EU co-funded data. The data controller commits him-/herself to have established the necessary to enable this.

For further description please see the Study Protocol (Annex 1) and the HBM4EU webpage on data management.

³ <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN>

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Table 3: Minimal requirements considering the sharing of HBM4EU co-funded data

Aggregated or Single measurement data	Format	Share	Accessible via	HBM4EU project group ⁴	EU Commission and EU Agencies	EU National bodies	General Public
Aggregated data <i>(that can be considered anonymous)</i>	HBM4EU format	<input checked="" type="checkbox"/> YES	<input checked="" type="checkbox"/> IPCHEM portal website	<input checked="" type="checkbox"/> YES	<input checked="" type="checkbox"/> YES	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> YES
		<input type="checkbox"/> NO	<input type="checkbox"/> HBM4EU repository	<input type="checkbox"/> NO	<input type="checkbox"/> NO	<input type="checkbox"/> NO	<input type="checkbox"/> NO
		<input type="checkbox"/> NO					
	Own format	<input type="checkbox"/> YES	<input type="checkbox"/> IPCHEM portal website	<input type="checkbox"/> YES	<input type="checkbox"/> YES	<input type="checkbox"/> YES	<input type="checkbox"/> YES
		<input type="checkbox"/> NO	<input type="checkbox"/> HBM4EU repository	<input type="checkbox"/> NO	<input type="checkbox"/> NO	<input type="checkbox"/> NO	<input type="checkbox"/> NO
		<input checked="" type="checkbox"/> NO					
Anonymised Single Measurement Data⁵	HBM4EU format	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> IPCHEM portal website	<input type="checkbox"/> YES	<input type="checkbox"/> YES	<input type="checkbox"/> YES	<input type="checkbox"/> YES
		<input type="checkbox"/> NO	<input checked="" type="checkbox"/> HBM4EU repository	<input type="checkbox"/> NO	<input type="checkbox"/> NO	<input type="checkbox"/> NO	<input type="checkbox"/> NO
		<input type="checkbox"/> NO					
	Own format	<input type="checkbox"/> YES	<input type="checkbox"/> IPCHEM portal website	<input type="checkbox"/> YES	<input type="checkbox"/> YES	<input type="checkbox"/> YES	<input type="checkbox"/> YES
		<input type="checkbox"/> NO	<input type="checkbox"/> HBM4EU repository	<input type="checkbox"/> NO	<input type="checkbox"/> NO	<input type="checkbox"/> NO	<input type="checkbox"/> NO
		<input checked="" type="checkbox"/> NO					
Pseudonymised Single Measurement Data⁶	HBM4EU format	<input checked="" type="checkbox"/> YES	<input checked="" type="checkbox"/> HBM4EU repository				
		<input type="checkbox"/> NO					
	Own format	<input type="checkbox"/> YES	<input type="checkbox"/> HBM4EU repository				
		<input checked="" type="checkbox"/> NO					

⁴ The option to make the data on the IPCHEM portal website accessible only to HBM4EU project group follows indications of Articles 10 and 11 of the IPCHEM Data Policy and related to “Use of IPCHEM for projects on chemical monitoring data”. This extraordinary project-specific accessibility rules can only last temporarily for the duration of the HBM4EU project. Upon the dissolution of the Project the data generated, collected or analysed in the course of the Project will have to be made accessible to IPCHEM User Groups according to the Open Data Principles and the Exceptional Accessibility Regimes described in Articles 4-7 of the IPCHEM Data Policy.

⁵ Preferred option, however when anonymisation is detrimental, pseudonymised single measurement data shall be shared.

⁶ Legal framework to ensure that the transfer of pseudonymised data by the Data Controller to the HBM4EU repository is GDPR compliant is currently being established.

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Considering the fieldwork, the following aspects are emphasised:

- ▶ The Data Controller is responsible to provide the necessary ethics and data protection documentation following the procedures outlined by Task 1.5. Approval to analyse the samples and use the data for HBM4EU research is requested.
- ▶ The Data Controller commits him-/herself to follow the HBM4EU procedures for sample and data transfer. This includes, but is not limited to, completing and signing the data transfer form and providing the completed metadata template.
- ▶ The Data Controller is responsible for ensuring in house data management of the data generated during the fieldwork is compliant with the General Data Protection Regulation (GDPR) and additional national regulations (when applicable).
- ▶ For data generated with HBM4EU co-fund, the Data Controller commits him-/herself to upload the data to the HBM4EU repository as single measurement data (including accompanying variables necessary for analysis and interpretation) and to make the data available to policy makers upon request.
- ▶ The Data Controller is responsible for the anonymisation or pseudonymisation process and for ensuring that identifiable variables are not transferred to the HBM4EU repository. Directly identifiable variables include – but are not limited to – national ID number, name, phone number, e-mail address, address, geographical coordinates (at a resolution that allows re-identification of study subjects). One shall also be aware that a combination of just a few indirect identifying variables (such as birth data, gender, and zip-code) can be sufficient to re-identify an individual in a dataset. In this context, the Data Controller shall only provide such variables at the lowest possible resolution that is necessary for analysis, e.g. district instead of zip-code; year of birth or age instead of birth date.
- ▶ The data management team (Task 10.1) will provide assistance in how to create unique HBM4EU identifiers for the samples. The HBM4EU identifier shall be used for labelling the samples (that are transferred for HBM4EU) and for labelling the data. The Data Controller is requested to provide details of the study design at least 4 weeks prior to the need of the identifiers. The Data Controller is responsible to securely store the key linking the HBM4EU unique identifier back to the individual.
- ▶ Data shall be transferred using a harmonised template and based on the HBM4EU codebook.

For subsequent data use of non-anonymised data in the HBM4EU repository by consortium partners, a data controller – data processor agreement between the data controller and the data user (i.e. the entity performing analyses on the data on behalf of the data controller) shall be established. The most important points of this agreement are:

1. A description of the data (i.e. the compilation of the metadata fiche);
2. A clear specification of the use of the data that should be in line with ethical permissions;
3. The duration of the processing;
4. List of required variables;
5. Description of the subset of the data: (e.g. specific age range, sampling period)
6. The commitment of both parties to work GDPR compliant;
7. A description of organisational security measures, and a commitment to destroy or handle the data back to the controller after the processing;
8. Identification of the people that shall be granted access to the data in the HBM4EU repository, to enable access based on EU id.

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A template agreement is currently under revision and will be made available soon.

Upon signed agreement, the data processors (lead data user and other data users) obtain the necessary permissions to access the data via a dedicated section on the HBM4EU repository and to perform the data analyses for the purpose specified in the approved proposal. Data analyses and presentation of papers should adhere the STROBE guidelines⁷. Data Processors can choose the software for data analysis, unless otherwise specified in the Data Controller – Data Processor Agreement.

Entering the HBM4EU repository, users accept the general terms and conditions. This includes, but is not limited to,

- ▶ not attempt to re-identify study participants identity,
- ▶ safeguarding to not share the data with unauthorised people (anyone not signed a data use agreement linked to the approved proposal);
- ▶ commitment to upload all derived variables, analysis pipelines, intermediate results, and/or results to the HBM4EU data repository upon analysis to a section of the repository dedicated to this agreement;
- ▶ commitment to not store the data on any place that is accessible by others;
- ▶ commitment to securely destroy all data related to the proposal stored outside the repository - including all possible back-ups as well as (intermediate) results from the analysis - at the latest at the end-date of the approved proposal;
- ▶ commitment to follow the procedures regarding publication and/or dissemination of results.

All details are available in the DMP and data policy on the HBM4EU website.

6.7 Communication

Studies performed in the frame of HBM4EU are in the full responsibility of the country conducting them. Until now there is no overarching structure like in DEMOCOPHES organising a definite start and conduct of several studies. As a consequence there is no common communication strategy – but there are recommendations, e.g. for a necessary communication strategy for recruitment and fieldwork (see Chapter 6.3 and the Study Protocol in Annex 1). Additionally, WP 2 and WP 4 provide general documents on HBM4EU aspects and substances and several helpdesks have been established. Task 7.5 focuses on communication material for participants and provides templates needed for the conduct of a study (see Deliverable 7.4).

Communication campaigns regularly aim to promote

- ▶ awareness,
- ▶ encourage stakeholder involvement and
- ▶ maximise recruitment and retention.

The initial campaign should therefore start as soon as the study protocol is ready and a website is available. Briefing of the policy makers should start at the same time. A kick-off event for the national study activities is an ideal time to communicate and to hold a symposium to which key national stakeholders should be invited.

Main aim is to maximise recruitment, i.e. to achieve a sample that adequately represents the target population, and within that, sufficient participants to reflect the target population. To this end communication is directed towards

⁷ STROBE stands for an international, collaborative initiative of epidemiologists, methodologists, statisticians, researchers and journal editors involved in the conduct and dissemination of observational studies, with the common aim of STrengthening the Reporting of OBServational studies in Epidemiology. See <https://strobe-statement.org/index.php?id=strobe-home> for more information.

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- ▶ the general public (press releases, news articles, website, social media)
- ▶ the target population (press releases, news articles, website, social media)
- ▶ participants (flyers, letters, face-to-face, website, newsletter)
- ▶ media (press release, conferences, social media)
- ▶ scientific community (flyers, posters, banners, publications/presentations, social media)
- ▶ policy makers (factsheets, statements, conferences, social media)

Several documents will be necessary for a clear communication with the participants, most important ones are named below and templates provided by Task 7.5:

- ▶ Invitation letter
- ▶ Information leaflet
- ▶ Informed Consent form
- ▶ Reply card
- ▶ Reminder letter
- ▶ Appointment letter and leaflet explaining e.g. taking of urine samples
- ▶ Results letter
- ▶ Letter of thanks.

It is important that the participants have plenty of opportunities to ask any question to encourage participation and to reduce withdrawal from the study. In all letters contact details, including name, address, telephone number and email address shall be given. Links to the national and HBM4EU websites should also be provided.

After the study, the dissemination of the results to participants (respecting the right to know and not to know), the general public, the science community and policy makers are important tasks of each study (for this see also the communication/publication strategy provided by WP 2).

6.8 Ethics and data protection

Without the authorisation of an ethics committee and partly separately the permission of the data protection officer (privacy authority) no HBM study can be performed. It is in the responsibility of the study owner to receive country specific authorisation and/or permission, respectively.

Forms to be submitted for ethical approval and notification, although following a similar logic, may differ from country to country. Therefore, the practical preparation of the ethical forms and privacy notification will be in the responsibility of the countries conducting the study. Task 1.5 is responsible for overarching HBM4EU ethics and data protection aspects and can support in case of questions.

The following documents are required to be considered for any studies under HBM4EU:

- ▶ D1.5 Legal and Ethics Policy Paper,
- ▶ D17.1 – D17.6 Ethic requirements (see Grant Agreement number 733032; page 111 of 128),
- ▶ First, second and following Ethics reports (see internal webpage work package folder/scientific and administrative management/WP1).

Task 7.5 has developed a template for the informed consent (see Deliverable 7.4). All activities of human biomonitoring studies further have to adhere to the legal and ethical framework established by several international directives, conventions, and guidelines and implemented in domestic laws. The ultimate objective is to guarantee an optimal protection of the rights and dignity of every data subject. Special attention will therefore be directed to:

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- ▶ The specified, explicit and legitimate **purposes of the study are defined** and explained to all actors involved;
- ▶ **Written consent** (informed, free, explicit, specific and documented) is asked prior to the commencement of research and includes:
 - Right to refuse consent or to withdraw consent at any time without giving reasons and without being subject to any form of discrimination;
 - Right to access to personal data and right to rectification of data;
 - Right not to know personal data.
 - The wish of volunteers (data subjects) to know or not to know is documented and a procedure put in place in case of unexpected findings are defined.
 - Confidentiality of data is assured by appropriate technical and organisational measures that must be implemented to protect personal data.
 - Indicated in the written consent form are also:
 - Identity of the data controller;
 - Purpose of the processing for which the data are intended ;
 - Recipients or categories of recipients of the data.
- ▶ **Processing of data is supervised** by a health professional (not always required).
- ▶ An **information leaflet** is provided with:
 - Purpose
 - Overall plan
 - Possible risks and benefits
 - Approval of the ethics committee
- ▶ **Communication of results** is planned at individual and at collective level.
 - Communication at individual level is provided in a framework of healthcare or counselling if needed.
- ▶ The meaning of the **results and potential health relevance will be explained** before the sampling, together with the uncertainty aspects.
- ▶ Submission to an **appropriate ethical committee** and notification to the appropriate 'Privacy Authority'.

Please bear in mind that application for ethics authorisation requires preparation of nearly all material intended for the communication with the participants and may as well need several weeks to months. It is important to inform that data and results will be shared within HBM4EU at individual level and in anonymised/pseudonymised form (see paragraph on data management. Within HBM4EU it is mandatory to provide the documents of ethics approval to Task 1.5 prior to initiation of the study to make the individual data available for HBM4EU.

6.9 Pilot study

It is highly recommended to test the processes for a designed study in a pilot study.

A pilot study is an 'investigation designed to test the feasibility of methods and procedures for later use on a large scale or to search for possible effects and associations that may be worth following up in a subsequent larger study' (Everitt 2006).

The pilot study's size is usually connected to the main study's size: If the main study is planned to include a small sample only, the sample size of the pilot study is fixed to enable testing of the main study instruments. Especially procedures with direct contact to the participant, e.g. questionnaires conduct and the collection and processing of samples shall be tested.

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A pilot study does not have to fulfil the same criteria as the main study regarding e.g. representativeness, it is simply a tool to assess if procedures and documents work as intended or if adjustments have to be made before the main study is carried out.

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7 Annexes

7.1 Annex 1: Concept for a Study Protocol

7.2 Annex 2: Fieldwork Manual Template

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7.2.1.1 Annex 2.1.1: Basic questionnaire for 1st priority substances

7.2.1.2 Annex 2.1.2: Interviewer Manual to the basic questionnaire for 1st priority substances

Annex 2.1.2.1: Summary table of ISCED 2011 codes and criteria

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Annex 2.1.2.3: Food serving sizes gallery

Annex 2.1.2.4: The Statistical classification of economic activities in the European Community, abbreviated as NACE (Type of industry/workplace)

7.2.1.3 Annex 2.1.3: Matrix-specific questionnaires to accompany the sampling of urine and blood

7.2.1.4 Annex 2.1.4: Interviewer Manual to the matrix-specific questionnaires (sampling of urine and blood)

7.2.1.5 Annex 2.1.5: Concept for the development of non-responder questionnaires in the scope of HBM4EU

7.2.1.6 Annex 2.1.6: Satisfaction Questionnaire

7.2.2 Annex 2.2: Standard Operating Procedures (SOPs)

7.2.2.1 Annex 2.2.1: SOP 1 - Selection of Participants and Recruitment

7.2.2.2 Annex 2.2.2: SOP 2 - Quality Assurance for Recruitment and Fieldwork

7.2.2.3 Annex 2.2.3: SOP 3 - Procedure for obtaining human samples

SOP 4 - Sample Exchange on a pan-European level to be used in the HBM4EU initiative

This SOP on 'Sample Exchange on a pan-European level to be used in the HBM4EU initiative' was produced within **Task 7.4**, led by Dominik Lermen (IBMT) can only be found attached to the deliverable of Task 7.4, D7.2.

It is considered an important SOP to be taken into account like the other SOPs attached directly to this deliverable.



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Annex 1

Concept for a Study Protocol focusing on Recruitment, Fieldwork and Sampling

WP7

Task 7.2

D 7.3

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Thanks to all partners of Task 7.2 and 7.3 who supported this Study Protocol.

This document has been created for the HBM4EU project. HBM4EU has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733032.

1 Introduction to the Study Protocol

HBM-studies in the sense of HBM4EU are epidemiological studies. According to the International Epidemiologic Association (IEA), "... the [study] *protocol is the cornerstone of any epidemiological research project. In this the purpose of the study, the hypotheses, the design, the source population, and the planned analyses are described. Administrative issues, ethical considerations and possible problems and limitations are also addressed in the protocol*" (IEA 2007).

The IEA also admits that it is not possible to present a standard structure for a protocol that could be used in all situations but all epidemiologic research should follow standards of good scientific practice. Such standards have been published i.e. from the American Chemical Manufacturers Association (Cook 1991) and by the German Society for Epidemiology (DGEpi), last updated 2008 (DGEpi 2008).

A kind of transformation of such guidelines is provided with this Concept for a Study Protocol developed by partners of Task 7.2 of the European Joint Programme HBM4EU. This Study Protocol does not cover all aspects mentioned above by the IEA, it does not have a comprehensive paragraph on the purpose of the study, the state of the art or on hypotheses – these parts could be added and may be important when applying for money and ethical and data permissions.

Task 7.2 provides a template or model for the conduct of human biomonitoring (HBM) studies **to be carried out in the frame of HBM4EU**. Primarily, this Study Protocol covers recruitment, fieldwork and sampling. It is intended to be used for new cross-sectional studies for the adult general population but with some adaptations it can also be used for any other HBM study or HBM part of e.g. health studies. It can also serve to check protocols from already ongoing studies which will be extended with some parts (aligned studies) to deliver comparable results in the frame of HBM4EU (tasks important for aligned studies are especially mentioned).

This template tries to address all steps that are worth consideration when preparing a HBM-Study. It has been developed hand in hand with countries participating in the initiative, taking into account information on existing experience and expertise gathered from the HBM4EU partners.

Previous international studies like DEMOCOPHES have proven that it is feasible to apply harmonised mandatory operational procedures (protocols) in several different participating countries, but a certain amount of flexibility to ensure successful adaptation of the study is needed. To take into account that in a first step for HBM4EU not one harmonised protocol will be followed and also to address the necessary flexibility sometimes alternatives are mentioned for some procedures in the following.

IEA and DGEpi also pointed out that the study protocol should always be available before the study starts to ensure the quality of the study. The study protocol is a compilation of the most important information necessary for the implementation, application, and evaluation of the study. To safeguard validity of data and good data quality it is necessary to follow such guidelines which build the basis for proper study conduct.

A study protocol usually starts with information on the background of the planned study. To serve this, Chapter 2 provides some information on HBM4EU. As it is not possible to prepare one study protocol valid for several studies but to support all who have to design a study, Chapter 3 explains the newly introduced Concept for a Study Protocol, splitting up the procedures for planning a study into five phases (Phase 0 to 4). In the subsequent chapters the different tasks of each phase are explicitly explained, making it easier to keep all necessary aspects for study conduct in mind. The chapters of the Phases 0-4 take over the function of a study protocol, i.e. all aspects which are mentioned in one phase have to be answered and elaborated for the study to be planned.

Please also consider more detailed information in deliverables from other tasks and Work Packages for a full view on important aspects of study conduct, like ethics (Task 1.5), data management (WP10), communication (WP 2 and Task 7.5) and analytics (WP9).

2 Aims of the European Human Biomonitoring Initiative (HBM4EU)

This study (*fill in the name of the study*) is designed to be conducted in alignment with the aims of the European Human Biomonitoring Initiative (HBM4EU). HBM4EU is funded by the European Commission under Grant Agreement No. 733032.

The overall objective of this study should always be in line with one or more of the following, overarching objectives as set out in the HBM4EU Description of Action Section 1.1:

- i. Harmonise procedures and tools for HBM at EU level;
- ii. Provide and, where missing, generate internal exposure data and link this data to aggregate external exposure and the relevant exposure pathways;
- iii. Develop novel methods to identify human internal exposure to environmental and occupational chemicals and establish the causal links with human health effects;
- iv. Provide policy-makers and the general public with science-based knowledge on the health risks associated with chemicals exposure; and
- v. Improve chemical risk assessment in the EU through the effective use of HBM data.

HBM studies performed under HBM4EU shall fulfil the overarching objectives of the programme, the harmonisation of procedures and tools for HBM methods at EU level as well as the generation of new and gap-filling representative exposure data. The aim is to provide policy-makers and the general public with science-based knowledge on health risks associated to chemicals exposure.

3 Phases Concept

Planning representative HBM-studies usually involves several organizational issues, the order of which is important to respect. A well-developed concept providing a good overview as provided with the Phases concept here can help keeping track of schedule and key players.

The idea of the Phases concept is to split up the planning and conduct of a study into different phases (planning, preparation, concretization, start, and fieldwork). Table 1 presents a rough overview which is explained in short hereinafter:

We discriminate between the Planning Phase (**Phase 0**) where all decisions for the study to be conducted are taken. This is followed by the Preparatory Phase (**Phase 1**) in which all necessary documents are prepared and lacking information is collected. In the following Concretisation Phase (**Phase 2**) the decided issues are started to be turned into practice, e.g. material bought or labs contracted. In the Starting Phase (**Phase 3**) first contacts for getting addresses are arranged; personal contacts and participant involvement follow in **Phase 4** (Fieldwork Phase).

Table 1 gives an overview of possible phases of a (HBM-) study and their characteristics to enable a smooth organisation. These Phases involve mandatory characteristics for new studies and optional characteristics for aligned studies – depending on the state and structure of the study to be aligned. Actually, some issues of single Phases may partly overlap. It is also possible to integrate more instruments than only questionnaires and urine/blood sampling e.g. sampling of drinking water. These additional instruments also have to be considered in each of the Phases.

Table 1: Phases of a study and its characteristics in general

	Characteristics
0 – Planning Phase	General decisions on: Study design, samples and biomarkers, participants, fieldwork, data management, budget
1 – Preparatory Phase	Prepare Study Protocol and start to prepare a Fieldwork Manual including SOPs for recruitment and quality assurance
	Prepare (and test) questionnaires (necessary for ethics) and prepare an Interviewer Manual
	Prepare analytics
	a) <i>identify labs</i> with adequate limit of quantification for selected substances and with successful results in the HBM4EU ICI/EQUAS scheme
	b) <i>check lab needs</i> regarding volume/amount of sample, conservation, time required for analysis, contract conditions, etc.
	c) <i>elaboration of Standard Operating Procedures (SOPs)</i> : All steps and materials required should be described in detail in the corresponding SOPs: for sampling, for sample conservation, for sample reception (including acceptance and rejection criteria), for aliquoting and for biobanking
	Prepare data management (necessary for data protection)
	a) for address holding and handling
	b) for tracking recruitment attempts
	c) for results of questionnaires and analytics
	Prepare communication material:
	a) to get in contact with contact persons for approaching potential participants (registration offices, school principals, etc.) (necessary for ethics)
	b) for all contacts to potential participants (necessary for ethics) including non-monetary incentives like information material, personal results letter, books/bags/toys with study logo
	c) to inform the community / general public
	Apply for authorisation
a) Ethics Committee	
b) Data protection agency	
2 – Concretisation Phase	Finalise the Fieldwork Manual including communication material, all SOPs and questionnaires
	Engage and train qualified field staff (interviewers)
	Prepare/organize and buy material
	a) for the sampling and aliquoting of the matrix to be collected
	b) as incentives/other measures to increase participation rate
	c) for the field staff
Fix timing of fieldwork (start/end/route plans)	
Contract labs for substance analysis	

<p>3 – <i>Starting Phase</i></p>	<p>Get addresses of potential participants (as decided in Phase 0) Inform the general public at the sampling location about the study Inform the labs of the near start of the study If appropriate: Acquire rooms as examination centres at the selected areas (sampling locations)</p>
<p>4 – <i>Fieldwork Phase</i></p>	<p>Invite potential participants, clarify their inclusion, fix an appointment, provide material to collect samples (Fieldwork I) Involve participants in the survey (interview, examination, samples, incentives, results) (Fieldwork II), mainly done by field staff. Quality assurance and control measures are included.</p>
<p><i>Subsequently</i></p>	<p>Sample analysis, combine results from questionnaires and chemical analyses, sign data transfer agreement and transfer data to secure server for storage and detailed data exploration, storage of biological samples (biobank), publications etc.</p>

When a country considers to conduct a new HBM-study first general decisions have to be made, e.g. concerning the study design, the participants and how to select them, how fieldwork shall be organized and what does it comprise of, which analytics (substances, biomarkers, matrices, volume and amount) shall be performed and, last but not least, which budget can be spent (this mostly is a prerequisite to decide on all other aspects). When these decisions of **Phase 0** – the Planning Phase - have been made (and this will definitely take a while!), the preparations of the concrete instruments can start (**Phase 1**, Preparatory Phase).

HBM-studies always need to be approved by an ethics committee and the data protection authority, but to be able to approach these authorities, questionnaires, communication material and a data management plan have to be intensively thought of and prepared because the authorities want to approve these materials (changes in format may still be possible). And maybe, before finalizing the materials, they should be streamlined with a corporate design and a logo for all the documents which may be developed. A Study Protocol and SOPs (for analytics and quality assurance of fieldwork) have to be prepared and the preparation of a Fieldwork Manual started. If questionnaires are developed (or translated) an Interviewer Manual which informs about the background/rationale of each question should be prepared. The information collected for the Interviewer Manual is also a good basis for preparation of the communication material for the participants. Conducting a study is rather complex: responsibilities for the single steps and issues have to be defined and assigned to selected persons, even a subcontract for several tasks is possible.

After these responsibilities have been settled, the Concretisation Phase can begin (**Phase 2**, Concretisation Phase), i.e. field staff (interviewers, if a face-to-face interview is planned) have to be hired and trained on all instruments. To conduct a study in a validated manner a Fieldwork Manual, consisting of blueprints of all necessary documents and clear descriptions of all instruments has to be finalised in Phase 2 and provided to every member of the staff. Devices and materials needed to be handed out to the participants or to the field staff or they have to be ordered and stored and the definite timing of the fieldwork has to be fixed and route plans elaborated.

Now the study is ready to start (**Phase 3**, Starting Phase), i.e. recruitment of potential participants begins with acquiring their addresses, e.g. from population registries. If required, rooms as

examination centres have to be rented and communication on the study to the general public can be launched.

After that, the real fieldwork starts with the direct contact to the individual participants (**Phase 4, Fieldwork Phase**). The first part of fieldwork (Fieldwork I) comprises individual contacts to potential participants (invitation, checking inclusion criteria, fixing appointments and sending sampling materials). The second part of fieldwork (Fieldwork II) includes working with the participants from the moment they really participate in the study, e.g. when they answer questionnaires or provide samples and receive their individual results. These procedures are accompanied by quality control measures to warrant high quality of the received results. When fieldwork is finished and samples analysed (which can already start parallel to Fieldwork II if the fieldwork takes some time) all data is subsequently assessed.

For **biobanked samples**, the Phases split up as described in Table 2. D7.2 delivers a strategy and SOPs for human sample exchange, including ethical demands.

Table 2: Phases of a study using biobanked samples and its characteristics

Characteristics	
0 – Planning Phase	HBM4EU decides on suitable biobank material, inclusion and exclusion criteria in relation to chemical of interest, sampling and storage conditions . Permission from biobank responsible person/PI has to be granted
1 – Preparatory Phase	<p>Check availability of informed consent (IC), does this cover transfer of samples within EU or outside EU? Or is a new IC needed?</p> <p>If appropriate: Prepare communication material for seeking new informed consent from participants</p> <p>Prepare data management files: sample and information coding and results</p> <p>Gather information associated with the biobanked samples</p> <p>Use questionnaire to collect basic information in a harmonised manner (pre-specified requirements defined by tasks: 7.2, 8.2, 11.2, 13.2) on e.g. study design, time frame, sampling material, questionnaire and additional relevant information</p> <p>Reassure sample and data availability according to inclusion criteria and research question, and within a defined time frame</p> <p>Apply for ethical approval (if not yet available) and data protection</p>
2 – Concretisation Phase	<p>Buy suitable material for aliquoting of biobanked samples (if needed), (Recommendations see Deliverable 7.3 SOP on sampling material)</p> <p>Appoint analysing laboratory, considering the results of the HBM4EU ICI/EQUAS scheme (subcontract needed?)</p> <p>Set up time schedule for sample withdrawal from biobank</p> <p>Get signatures for the sample and data transfer agreements (according to D7.2 Annex 1 (SOP 4))</p>
3 – Starting Phase	<p>Transport to predefined lab (according to Task 7.4 SOP on sample exchange, see D7.2) including documentation of transport conditions</p> <p>Transfer sample related data to study PI and data manager</p>
4 – Fieldwork Phase	For samples already in a biobank there is no fieldwork
Subsequently	<p>Perform chemical analyses in laboratories with successful results in the HBM4EU ICI/EQUAS scheme</p> <p>Transfer analytical results to data manager (HBM4EU repository)</p>

Specific Phases for **aligned studies** are described briefly in Table 3:

Table 3: Specific Phases of an aligned study and its characteristics

	Characteristics
0 – Planning Phase	Identify suitable ongoing studies (Task 8.1A) which include basic requirements for HBM4EU studies
	If suitable ongoing study is identified: Define the type of extension needed (new and/or additional biological samples, additional information from questionnaires, registers or clinical examinations)
1 – Preparatory Phase	Seek permission from responsible person/study, this needs to be granted
	Determine if additional HBM samples and/or information (questions, examinations) can be collected. If yes, follow procedures for new studies (from Phase 1 or 2 onwards)
	Additionally: Inform staff and study participants of the proposed extension

In the following Phases 0 to 4 are described in detail.

3.1 Phase 0: Planning Phase

The Phases concept starts off with a Planning Phase addressing all decisions that have to be taken in advance pertaining different elements of the study like study design and biological samples, selection of participants, recruitment and fieldwork.

All actions the following phases require need to be considered and their execution decided upon already well before the study can start.

General topics to be decided upon are listed in Table 4. A detailed explanation of these general topics follows closely after.

It is important to consider the **conduct of a pilot study** to try out the instruments defined in the Planning Phase. A pilot study tests the feasibility of methods on a smaller scale in order to adjust processes or study material for the main study.

Table 4: General topics to be decided on in Phase 0 of a study

1. Study design and biological samples	• Aim for representativeness (sample size)
	• Type (cohort, case control, cross-sectional?)
	• Timing, Duration, Follow up?
	• Substances and their biomarkers
	• Matrices, sampling time (first morning urine/24h ?)
	• Sample volume
	• Biobanking
	• Ethics and data protection
2. Selection of participants	• Data management
	• Target population
	• Sampling frame
	• Geographical distribution
3. Recruitment and Fieldwork I (individual recruitment)	• Inclusion / exclusion criteria
	• Communication
	• Approach to address holder
4. Fieldwork II (investigation of participants)	• Method and frequency to approach participants
	• Instruments to be applied (Questionnaires, Samples (blood, urine, indoor air, drinking water, etc.))
	• Place of direct contact to participants
	• Questionnaire(s) application
	• Sample collection and further processing including sample conservation and shipment
	• Selection of the laboratory
	• Incentives

3.1.1 Phase 0: Study design

3.1.1.1 Representativeness

To achieve European representativeness within HBM4EU it is important that studies conducted in the participating countries also build upon representative samples. Decisions have been taken regarding the way how European representativeness shall be obtained within HBM4EU (Details please see Chapter 4 “Strategies for recruitment and sampling to attain EU representativeness” in D8.1). The way to obtain a representative sample depends among others on the target population. Table 5 lists the best ways to achieve a representative sample in different population groups.

Table 5: Methods for obtaining a representative sample in different population groups and their sampling frames

	Sampling frame (to select from the list of...)	Methods for obtaining a representative sample
General population of adults with or without children or only children (separated by gender and/or age)	Population register (country, regional)	1) Perform random sampling, keep track of non-responders and drop outs 2) Extract from ongoing study
Vulnerable population (pregnant, newborns, seniors, etc.)*	Patient files of clinics/doctors/midwives	Perform random sampling, keep track of non-responders and drop outs
Occupational population (partly)	Employment records, branch organisations, large cohorts	1) Prepare a list of eligible sampling units (work places) for random sampling 2) Extract from large database/cohort
Children /adolescents (different age groups)	Kindergartens/day care centres, or their groups Schools, vocational schools, or classes	Prepare a list of eligible sampling units (schools, day care centres) for random sampling

*Very often vulnerable populations are contacted directly, e.g. pregnant women when they arrive at the clinic before delivery. This approach is susceptible for selection bias if it is not taken care of that the selection of the premises to be approached were selected randomly (or fully) and that statistical procedures are regarded. See also 3.1.4.3 Sampling frame.

3.1.1.2 Type of study

Decisions on the type of the study have big implications on each aspect of the study conduct but also on the scientific significance especially if elucidating causality is aimed at. In the timeframe given for the HBM4EU project it only seems feasible to conduct cross-sectional studies which include the possibility of a longitudinal follow-up. Cross-sectional studies provide a snapshot of the exposure or health experience of a population at a specified time and are therefore often used to describe patterns of disease occurrence (Kleinbaum et al. 1982), i.e. cross-sectional studies provide information on exposure and disease frequency at the time of the sampling.

In the 2011 pilot study DEMOCOPHES that tested the feasibility of a pan-European HBM study the cross-sectional study design was already used (Joas et al. 2012, Den Hond et al. 2015).

Given the general knowledge and experience with the conduct of cross-sectional studies gathered in the HBM4EU consortium combined with the restricted time frame and the fact that this type of study design allows for representative results which can answer to some raised policy questions, a new study under HBM4EU should be preferably planned as a cross-sectional study.

Biobanked samples can be taken from different kind of studies, cross-sectional studies, cohorts or case-control studies (just to mention the main study types). The same accounts for studies to be aligned. For biobanked samples, D7.2 should be considered.

3.1.1.3 Timing and Duration

The point in time at which a study is started and how long its phases will take (especially the fieldwork) has implications for the representativeness and for organizational aspects of the study. There are some alternatives listed in Table 6. Most favourable for calculation of reference values or other types of data analyses is including seasonal variability possible in longer lasting studies. Studies just covering one season may provide biased results and may need more personnel if many participants shall be included. Studies may also foresee a follow-up some months or years later (even though exceeding the time frame of the HBM4EU project).

Table 6: Alternatives for the timing and duration of fieldwork within a study

	Alternatives	Pros	Cons
Timing/ Duration of fieldwork	Within one season	No seasonal bias; early results	Organisational effort in case of many participants and face-to-face interviews
	Covering some seasons	Organisation convenient for field staff	Seasonal bias
	Covering all four seasons	Seasonal bias can be avoided through logistic measures and a long fieldwork phase	Long lasting study; organisational effort due to length of study

3.1.1.4 Ethics and data protection

To ensure compliance with ethical standards, it is mandatory to submit a proposal for the conduct of each planned study to an ethics committee. Further it is mandatory to ask for permission of the data protection authority. The planning of the study (done in Phase 0) has to be in accordance with the ethics committee and the data protection legislation of the participating countries and their requirements have to be taken into account, as well as the EU General Data Protection Regulation (GDPR, Regulation (EU) 2016/679). It is important to inform that data and results will be shared within HBM4EU pseudonymised at individual level and also in anonymised form (see paragraph on data management below). Each ethics committee and data protection agency has its own rules of procedures and templates which have to be followed. The application process can be rather long (four weeks to several months), therefore it is recommended to approach the relevant authorities early in the planning phase. Within HBM4EU it is mandatory to provide the documents of ethics approval to Task 1.5 as early as possible to make the individual data available for HBM4EU.

An important document for ethics approval is the informed consent which the participant (and/or the legal guardian) has signed to ensure his/her assent to the procedures. Task 7.5 has provided a template for the informed consent ensuring compliance with the requirements on European level by HBM4EU (see Deliverable 7.4).

The following documents, prepared by Task 1.5, have to be considered for any studies under HBM4EU:

- ▶ D1.5 Legal and Ethics Policy Paper,
- ▶ D17.1 – D17.6 Ethic requirements (see Grant Agreement number 733032; page 111 of 128),
- ▶ First, second and following Ethics reports (see internal webpage work package folder/scientific and administrative management/WP1).

3.1.1.5 Data Management

Data management is an important part of each study which includes several decisions about the way how data shall be managed and processed. Studies in the frame of HBM4EU agree to share their data within HBM4EU. Therefore Task 10.1 has developed a **Data management plan (DMP)** which has to be followed. The DMP describes the data management life cycle for all datasets to be collected, processed and/or generated by the research project (to be reached via <https://www.hbm4eu.eu/data-management/>). As a separate attachment to the DMP, the HBM4EU data policy has been designed. **The procedures described in the HBM4EU data policy shall be followed by all members of the consortium** and ensure that data on human subjects are transferred and used in a secure setting; that use of the data is compliant with ethico-legal requirements (including signed informed consent, ethics approval, and the applicable data protection laws, furthermore the EU data protection regulation, which is applicable from May 2018);

and that the use of both existing as well as new data occurs in agreement with the Data Controller (when applicable, for personal data) or Data Owner/Data Provider (in other cases). Management of datasets that include personal information and health information of study participants will be compliant with the General Data Protection Regulation (GDPR, Regulation (EU) 2016/679). The GDPR is a regulation by which the European Parliament, the European Council and the European Commission intend to strengthen and unify data protection for individuals within the European Union (EU). It applies for the exchange and use of personal data. Anonymised data are not considered personal data, while non-anonymised (including pseudonymised) data are. Hence, the HBM4EU data policy discriminates between the sharing of anonymised and pseudonymised¹ data.

Sharing of data includes exchange of data within HBM4EU. When possible, it is preferred that data are anonymised before exchange. When anonymisation is detrimental to the study and/or to answer the research question, the established procedures to exchange non-anonymised data, i.e. personal data, shall be followed. To reduce the risk of re-identification, it is requested that such data are at least pseudonymised before exchange.

Anonymised data – IPCHEM portal website

The **IPCHEM portal website** (<https://ipchem.jrc.ec.europa.eu/>) enables to search, access and retrieve **anonymous chemical occurrence data**. It is possible to share the data either with the general public or with subsets of users (user groups). Possible user groups are HBM4EU project group², EU Commission and EU Agencies, EU National bodies, and General Public. More information on the user groups can be found at the IPCHEM portal website³.

If a user group is granted access:

- ▶ All members of the group can use the data for any purpose they want
- ▶ No agreement between data provider and data user for downloading and using the data⁴.

Pseudonymised data – HBM4EU repository

To exchange pseudonymised data within HBM4EU, the **HBM4EU data repository** (<https://ipchem.jrc.ec.europa.eu/share/>) shall be used. The HBM4EU data repository is part of the IPCHEM platform and ensures safe transfer, storage and access of the data. It is highlighted that, according to the GDPR, sharing of non-anonymous data – and hence pseudonymised data - requires a specific prior **agreement between the data controller⁵ and the data processor⁶**, stipulating the rights and obligations of both parties. Template agreements are currently under revision and will be shared soon via <https://www.hbm4eu.eu/data-management/>. The legal framework to ensure that the transfer of pseudonymised data by the Data Controller to the HBM4EU repository is GDPR compliant is currently being established.

¹ Pseudonymisation means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.

² The option to make the data on the IPCHEM portal website accessible only to HBM4EU project group follows indications of Articles 10 and 11 of the IPCHEM Data Policy and related to “Use of IPCHEM for projects on chemical monitoring data”.

This extraordinary project-specific accessibility rules can only last temporarily for the duration of the HBM4EU project. Upon the dissolution of the Project the data generated, collected or analysed in the course of the Project will have to be made accessible to IPCHEM User Groups according to the Open Data Principles and the Exceptional Accessibility Regimes described in Articles 4-7 of the IPCHEM Data Policy.

³ Article 5. IPChem User Groups” of “IPChem – The information Platform for Chemical Monitoring: Data Policy, Date: 25/07/2016 , Version:2.3.

⁴ However any user “shall acknowledge the source of chemical monitoring data retrievable through the IPCHEM platform whenever such data are used” according to Article 12 of the IPCHEM Data Policy.

⁵ The Data Controller is the person who determines the purpose and means of the processing of personal data.

⁶ The Data Processor is the person who processes personal data on behalf of the Data Controller.

The Data Controller is responsible for the pseudonymisation process and for ensuring that directly identifiable variables are not transferred to the HBM4EU repository. Directly identifiable variables include – but are not limited to – national ID number, name, phone number, e-mail address, address, geographical coordinates (at a resolution that allows re-identification of study subjects). One shall also be aware that a combination of just a few indirect identifying variables (such as birth data, gender, and zip-code) can be sufficient to re-identify an individual in a dataset. In this context, the Data Owner/Data Provider shall only provide such variables at the lowest possible resolution that is necessary for analysis, e.g. district instead of zip-code; year of birth or age instead of birth date. The HBM4EU codebook (section: Data Format) has implemented such strategies to reduce the risk of re-identification.

In case the study coordinator is not a data controller, contact details of the data controller(s) need to be provided.

In well justified cases, one can opt to use the HBM4EU repository to share data that are not subject to GDPR legislation (aggregated data, anonymized single measurement data). In that case, the data owner or mandated data provider shall notify the IPCHEM Team (ipchem-support@irc.ec.europa.eu) by sending the identity of the people that shall be granted access to the data. In case an agreement between the data owner and the data user is desired, the data provider is responsible for establishing one (templates are not foreseen by HBM4EU).

Data Format

Metadata of all HBM data sets used in HBM4EU must be integrated in the IPCHEM portal website and made accessible to all user groups to ensure that the datasets are findable. The metadata shall be provided by filling out the **HBM4EU IPCHEM metadata template**.

For **anonymised** as well as for **pseudonymised data** it can be opted to provide data in **own format or in HBM4EU format**. For HBM4EU co-funded data, single measurement data and aggregated data are to be transferred in **HBM4EU format** using the HBM4EU data template and analysis script (R) respectively. This will enable comparison between data collections and between analyses. Only the transfer of additional variables that may be needed to answer a specific research question is allowed in **own format**

Guidance, templates and an example are provided via <https://www.hbm4eu.eu/data-management/>.

3.1.2 Minimal requirements considering the sharing of HBM4EU co-funded data

Data Providers shall complete the Data Transfer Form, in order to indicate the format of the data and the conditions under which they agree to make the data accessible via the IPCHEM portal website and via the HBM4EU repository. Table 3 in **D7.3 (main document)** provides a pre-checked table with the minimal requirements for sharing of HBM4EU co-funded data. The data controller commits him-/herself to have established the necessary to enable this.

In the Planning Phase of a study it is important to note – as stated above - that data generated within HBM4EU and for which HBM4EU co-funding is used to generate them, shall be made available for HBM4EU research (across all pillars and WPs) as single measurement data (individual records) and shall be made available to policy makers upon request. Together with the chemical measurement data, the accompanying variables that are needed to enable dedicated analysis shall be made available as single measurement data. These requirements shall be taken into account when applying for ethics approval and (when applicable) data protection approval to ensure that they can be fulfilled. The HBM4EU data transfer form shall be completed and submitted together with a filled out metadata template (HBM4EU harmonized). Data generated with HBM4EU co-fund shall be uploaded (in accordance with the HBM4EU codebook) to the

HBM4EU repository through which they are made accessible to other HBM4EU consortium partners. When using HBM4EU-cofund, the data controller shall ensure that this is possible. Access to and permission to use the data is only permitted upon data controller – data processor agreement. The latter is the entity performing analyses on the data on behalf of the data controller. The most important points of this agreement are:

1. A description of the data (i.e. the compilation of the metadata fiche);
2. A clear specification of the use of the data that should be in line with ethical permissions;
3. The duration of the processing;
4. List of required variables;
5. Description of the subset of the data: (e.g. specific age range, sampling period)
6. The commitment of both parties to work GDPR compliant;
7. A description of organisational security measures, and a commitment to destroy or handle the data back to the controller after the processing;
8. Identification of the people that shall be granted access to the data in the HBM4EU repository, to enable access based on EU id.

All information and templates regarding HBM4EU Data Management are available via <https://www.hbm4eu.eu/data-management/>. The helpdesk on data management is available to support and advice you in data management related tasks of WP10 (internal webpage: https://www.hbm4eu.eu/privatehelp-desks_trashedwp10-help-desk/).

3.1.3 Phase 0: Biological Samples / Analytics

In the Planning Phase decisions on the substances of interest have to be taken. Part of this decision has already been taken by HBM4EU. In a first prioritization round in 2016/2017 HBM4EU has prioritized 9 substances/ substance groups for which European data is needed: 1) Phthalates, DINCH; 2) PFAS; 3) Flame retardants; 4) Cd, Cr; 5) PAHs; 6) Anilines, MOCA; 7) Bisphenols; 8) mixtures and 9) emerging chemicals. A next prioritization round runs in 2017/2018. (New) surveys shall be conducted to fill identified data gaps. Countries still have to decide which of the substances they want to analyse. The selected substances determine the matrix (urine, blood, etc.), the volume of the matrix needed for one analysis (regarding the intended LOQ) or even the sampling time (substances with short or long half-lives). Further decisions pertain the whole volume of the matrix collected from the participants, sampling vessels and the number of aliquots to be derived and analysed or stored and the number of fieldblanks to be taken.

All these decisions have main impact on the fieldwork, the questionnaires and even the study design. Depending on the half-live of the target chemical in the selected matrix the time of sampling (morning / evening; distance of time to last meal) for that matrix should be taken into account, and this way it can have consequences to the way fieldwork should be scheduled. The decision on the necessary number of participants for a representative sample is based on statistical power calculations and therefore based on the selected substances.

It also has to be decided what happens with the samples in the field (directly send to a lab (which lab?) or handled/stored at the sampling location). In the Planning Phase also decisions on the material of the tubes and sampling bottles have to be made. Also, conservation of samples during and after fieldwork and transport conditions to the laboratory or biobank have to be taken. Some recommendations on such decisions are provided in Table 7.

Table 7: Recommendations for material for sampling and aliquoting

	Recommendations
<i>Material identification</i>	Dependent on: the biological matrix and the target analyte, the volume / quantity of the sample, etc. Advise: check the possibilities available in the market (the material of which is made of, the size, cost, availability, etc.)
<i>Material selection</i>	Considerations: the additives to preserve the sample, avoid specific material depending on the target chemical, test background contamination and/or take precautions if necessary, etc.
<i>Aliquoting</i>	The same recommendations as for the sampling material and additional ones: <ul style="list-style-type: none"> • ensure the material stability during the storage in the conservation conditions. • check stability of the samples during the conservation • check the quality of the labels identifying the frozen aliquots • define the proper volume of the aliquots to avoid unnecessary freeze/thaw cycles.

A decision has to be taken where the analyses of the collected samples shall be performed, which are qualified labs for the selected substances. For projects in the frame of HBM4EU samples should be analysed in laboratories that achieved successful results in the ICI/EQUAS scheme provided by WP9. Additionally, if the laboratory is not a member of the HBM4EU EJP it will be necessary to make use of subcontracting.

Within HBM4EU WP9 is the counterpart for analytical issues, please see specific deliverables. Some SOPs for pre-analytical aspects concerning sample taking are attached to Deliverable 7.3 as part of the Fieldwork Manual.

3.1.4 Phase 0: Selection of participants

A Study Protocol needs to provide information on the selection process on participants for the respective study.

Within HBM4EU the selection of participants follows developed guidelines taking already existing data of HBM4EU partners on the first priority substances into account. The next paragraph describes the selection process for HBM4EU on EU level.

3.1.4.1 Selection of countries and target population within a country

To set up a multistage probability sampling method in EU, **each participating country in HBM4EU is set as a primary sampling unit (PSU)**. To attain an entire European coverage within HBM4EU, a European maximal scenario would be sampling in each of the participating EU countries. To ensure sampling feasibility and due to financial constraints, the number was reduced to 12-15 European countries. These countries need to be distributed over all geographical regions in Europe. **Four geographical regions (clusters)** are defined according to the United Nations geoscheme for Europe: Northern Europe, Eastern Europe, Southern Europe and Western Europe.

The sampling domains for which at least specified reliability is desired in Europe are **gender and age groups**. The seven age groups that are targeted within the HBM4EU surveys are: 0-2y, 3-5y, 6-11y, 12-19y, 20-39y, 40-59y, 60-79y.

In each participating country, and for each of the selected age groups, we propose to **include 150 male and 150 female participants**. The sample size was chosen to ensure also inclusion of participants from different socio-economic strata and from different community sizes (urban, suburban, rural). To include different socio-economic classes, education level can be used as a proxy (International Standard Classification of Education (ISCED), which includes 9 levels of education (ISCED 2011, see task 7.2 report). The sample size is indicative and may need further adjustment for the specific chemical group because of expected population variability of the biomarker. Considering the geographical locations, inhabitants from urban, suburban and rural

areas are accepted. Hot spot areas, with known historical/actual environmental contamination need to be excluded.

In summary: to calculate EU reference values samples and data are collected in minimally 12 countries, with 3 countries per geographical region. Per country and per age group 150 males and 150 females are included. This results in minimally 3600 EU participants. Other possible sampling schemes are shown in Table 8. The schemes are applicable to newly collected as well as biobanked samples. In Task 8.1 EU study alignment will be done for the EU-wide exposure assessment to the HBM4EU priority substances to be measured in specific age groups among 12 countries over the 4 EU geographical regions mentioned above (scenario on 3rd line of Table 8).

Table 8: Possible sampling schemes for HBM4EU surveys, tailored to specific objectives.

The strategy which we recommend, is indicated **in red with an asterisk (*)**. (SSU: secondary sampling unit i.e. province, city, municipality, etc.) (also see updated Deliverable 8.1)

Scenario	No of countries	Sex	No of age groups	No per subgroup	Total number of participants
<i>Objective: sampling frame to assess exposure in Europe or difference between countries/regions</i>					
Actual EU-wide exposure in all age groups (complete scenario)	26	2	6	150	46,800
Actual EU-wide exposure in all age groups (reduced scenario)	12	2	6	150	21,600
Actual EU-wide exposure in specific age group (*)	12	2	1	150	3,600
<i>Objective: Time trends follow-up</i>					
Time trends follow-up in Europe	12 ^a	2	1	150	3,600
Regional time trends follow-up (*)	4 SSU^a	2	1	150	1,200
<i>Objective: Impact of policy</i>					
Impact of policy within a country	1 (before & after)	2	1	150	600
Impact of policy differences among countries (*)	3 (no, median, strict policy)	2	1	150	900

^a with the precondition that for the selected country/SSU at least two previous time points of exposure data are already available.

(*) the sample size for representative sampling needs to be adjusted according to the samples sizes needed for the specific chemical group because of expected population variability of the biomarker.

3.1.4.2 Inclusion/exclusion criteria

As mentioned above, 300 individuals, from each of the age groups, including males and females need to be recruited from the general population (exclusion of hospitalized individuals). No further general inclusion and exclusion criteria are set for studies in the frame of HBM4EU. However, for specific biomarker measurements, additional recruitment and sampling conditions may be set out. Furthermore, following minimal information needs to be collected (in the basic questionnaire), to have an indication of the population included:

- ▶ Life style: information on smoking and alcohol/drugs use, diet, housing conditions, hobbies and occupational exposure
- ▶ Socio-economic status needs to be documented (using the ISCED education levels)

- ▶ Residential history: number of years living in the country need to be reported
- ▶ Geographical coverage: urban/sub-urban/rural
- ▶ Sampling time period needs to be reported i.e. no seasonal restrictions are set.

3.1.4.3 Sampling frame

The sampling frame is the list of the target population units from which the sample is drawn. The frame should be defined in a way to achieve a representative population composition of that subgroup. As such the sampling frame depends a lot on the chosen target population, e.g. general population by population registers, school children by schools, working population by companies, newborn-mother pairs by maternities/hospitals. The way of recruiting the participants is not prescribed within HBM4EU. However, a good sampling frame model for selection of individuals is the stratified clustered multi-stage design. Via this design, geographical areas (stratification) are selected within a country. Within each of the geographical areas, primary sampling units (PSU: schools, work registries, general practitioners) are selected randomly, however that can be done in a way that there is an increased selection chance proportional to the number of individuals in these PSU. Furthermore, individuals are selected randomly within the PSU.

3.1.5 Phase 0: Recruitment and Fieldwork I

After decisions on the target population and the sampling frame have been taken, decisions on the general recruitment and the individual contact to the potential participants are up next. An important aspect within the issue of recruitment of participants is the communication: Who shall be contacted in which way? Suitable communication is key when aiming to ensure a successful contact to the participant and to reach acceptable participation rates (Exley et al. 2015).

Table 5 provided an overview of possible sampling frames informing about where the address of the potential participant can be obtained. To get the addresses, population registers, clinics or doctors or employers or the head of institutions (schools, kindergartens) or education authorities have to be approached formally with an official letter explaining the study and the aim of the approach.

General ideas that have to be considered for decisions on the timing and duration of the study are shown in Table 6.

Table 9 provides an overview of recommendations for the general communication with different groups. Specific templates for most of the recommended documents will be provided by Task 7.5 in deliverable D7.4 or D7.7.

Table 9: General communication

Groups	Recommendations for communication measures/material
Adults general population, occupational groups, vulnerable groups	Implement communication strategy presenting the specific study and the general HBM4EU framework, spread it via media + internet + the specific centres involving target participants. Provide information leaflets and hand-outs describing aims, structure and detailed participation arrangements of the survey → sent by mail or other approaches as appropriate, for occupational groups: make it available at the workplaces, workers' clubs and recreational facilities, trade unions offices), for patients make it available at the hospital facilities /outpatient clinics /community centres
General information	Press releases/videos (in national and regional newspapers and other media including Internet website), flyers, newsletters, posters, banners, study information leaflets at general health practitioners/health centres, for occupational groups: at workers offices and clubs, trade union offices
Individual information	Invitation letter, participant information sheet, consent form

Groups	Recommendations for communication measures/material
Children /adolescents (different age groups)	Provide preparatory meetings with school administrators, teachers/educators, and children's parents, before and during recruitment phases, with distribution of information leaflets and hand-outs describing aims, structure and detailed participation arrangements of the survey and the general HBM4EU framework
General information	Flyers, posters, study information leaflets at kindergarten/schools, parent's residence, articles in local newspapers and TVs, newsletters
Individual information	Invitation and information material sent to parents or/and to teachers; consent form from parents and also from children starting at age 10-12

Decisions on the fieldwork of the study and its timing also include decisions on communication and vice versa therefore already at this planning stage implications of the communication aspects are important to know (Exley et al. 2015, Fiddicke et al. 2015). In Table 10 some general recommendations on method and frequency to approach participants are given (Bates et al. 2005, Keune et al. 2008, Fiddicke et al. 2015, Mindell et al. 2015).

Table 10: Method and frequency to approach participants

Groups	General recommendations I
Adults (general population)	<p>Individual invitation letter</p> <ul style="list-style-type: none"> - <u>Personalized</u> invitation at least 3-4 weeks before the examination date - Invitation to include the date of the proposed appointment (possibly including a return card to book the appointment, or to modify the proposed appointment) - Reminder of the appointment (e.g. with text message/SMS) - Length of questionnaire influence (negatively) the participation rate depending on the type of questionnaire application (before or during the examination, web-based and in advance, etc.) <p>In case of no reply by study participants within 3 weeks, follow-up with phone calls and/or a second reminder letter offering a new appointment time (max. 6 additional contact attempts)</p>
Vulnerable population (pregnant, new born, senior, etc.)	<p>The invitation should be highly personalized and endorsed (or sent) by a confident person (GP, Paediatrician, Gynaecologist, Midwife Hospital/Clinic, Health Centre, Maternity/Lactarium).</p> <p>Home visit instead of meeting at the survey office should be considered.</p>
Occupational population (partly)	<p>Similar indications than for the adult population.</p> <p>Preliminary agreement about appointment time and survey approach methods with the participant employer and/or with the employee organization, at least one month before the survey date.</p>
Children /adolescents (different age groups)	<p>Similar indications than for the adult population, but request for participation and survey information should be addressed to both children/adolescents and their parents. Preliminary agreement about appointment time and survey methods with the school administrators and teachers/educators, as well as participant parents, at least one month before the survey date.</p>

3.1.6 Phase 0: Fieldwork II

In Phase 0, decisions to be taken related to the personal involvement of participants can be derived from following five main questions:

- ▶ **What** does the study ask from the participants?

This addresses the question on **which instruments shall be applied** to the participants. It is of importance here to clarify and settle every aspect that is asked from the participants, be it samples taken from them or their home or their time. Ethics aspects must be included in the considerations.

Some aspects can be invasive (depending on the **matrix**, the volume and amount of samples to be taken), others can present a burden by being time consuming or touching their privacy (dust samples).

Most of the time spent would most likely be on the **questionnaire**, self-administered or through face-to-face-interviews, needed to collect information on possible exposure pathways. The questionnaire mainly covers topics of living conditions and habits/lifestyle, health, nutrition, socio-demographics, occupation and should have additional modules: substance specific, non-responder and satisfaction questionnaires. The scientific curiosity has to be balanced with the time burden questions put on participants.

Additionally, **medical parameters** (weight, height, blood pressure, etc.) as well as markers of physical condition (ECG, lung function, etc.) might need to be examined directly from the participants. And some studies add **additional sampling** like dust, indoor air or drinking water samples. Again, this puts time and inconvenient burdens on the participants which have to be considered as they may influence the participation rate, too.

All samples taken will probably need to be processed already at the sampling location, this also needs to be considered.

- ▶ **How** long will the participants be occupied with survey demands?

This question pertains to the whole duration of fieldwork. It involves all aspects addressed above like physical examination, questionnaire (self-administered or interview) but additionally time spent to stay in contact with the study organisers. This also includes if the participant shall be involved just one time or several times within the study (or a follow up).

- ▶ **When** will the survey be conducted and the participants involved?

The period of time for the whole fieldwork phase should be settled beforehand. The decision should be preceded by considerations of target group and their respective occupation (e.g. a study planned to involve school children mainly at the schools should not take place during holidays).

- ▶ **Where:** At which site will the participants meet the study, what is the **place of direct contact** to the participants?

Commonly used options to encounter the study field staff are the home of the participants or a place of productive hours (work place, school, kindergarten). Official examination centres can be organized in schools, clinics, town halls, etc. or mobile labs can be the site to meet the participant. It is advisable to offer alternative possibilities to the participants if appropriate for the study instruments. If, e. g. additional samples from the home of the participants (like indoor air or drinking water) are part of the study or the questions of the questionnaire need expert judgment on living conditions a home visit is recommended.

- ▶ **What** will the participants receive for their burdens/contribution?

In order to keep up participation rates, it is important to ensure the participant is aware of their advantage when taking part in the study therefore they can be offered incentives. **Incentives** can be information on study and general or individual-level results as well as financial and in-kind rewards (reimbursement for travel costs and/or for spending time and samples) or small gifts and certificates for participation (see Table 11). The feeling of 'personal involvement' with the study by participants can be increased by inviting them to provide input and suggest research questions or even participate in the research.

More specifically, various forms of incentivizing study participants exist, and the selection has to be individually tailored to the specific study population. Depending on the expected barrier to enrolment/participation, such incentives could comprise organizational aspects including additional

information (e.g., home visits, direct mailings, etc. see Table 11 for additional examples) or support in recruitment through reduction of administrative burden or similar measures. It is advisable to think through the enrolment process and participation to identify potential barriers upfront, and think about ways how these could be addressed. However, the process of deciding which incentives, especially as they regard organizational aspects of the study, to apply, should remain flexible throughout the active phase and should be prepared to address any newly emerging barriers or needs as they evolve.

In addition to organisational incentives, monetary and non-monetary incentives should be considered and chosen, if there is an anticipation that they could help increase participation. Such incentives typically comprise either reimbursements of expenses that participants incur due to their study participation (e.g., travel cost), or small gifts that can be tailored to the specific target population (e.g., smaller wearables for younger participants, gift cards for adult participants, etc.). Here, the expertise and insight of peers or stakeholders from the respective population can be drawn upon.

With regard to incentives, decisions also have to take ethics permissions into account. Incentives can be provided (partly) before and after involvement in the study. Small (monetary) incentives provided with the first invitation can increase the participation rate. Which incentives are to be expected when participation is finished shall be addressed in the first information.

Table 11: Types of common incentives

Type of incentive	Incentives and other measures to increase the participation rate and their impact
Information (see also Phase 1+3)	Raise interest and awareness, offer information on study and general results, direct mailing, home visits, provide individual results and advice
Support recruitment	Choose suitable recruitment places (schools, work) Reduce the administrative burden of address holder (e. g. GPs) to encourage them to recruit participants Link HBM study to on-going routine surveys etc.
(Non-)Monetary	Reimburse participants for travel costs and/or for spending time and samples Offer cash payments or in kind payments (small gifts) or certificates for taking part
Staff as promotor	Sustain staff commitment to the research through continuing training (see also Phase 4)
Evaluation (see also Phase 4)	Identify barriers to participation, non-responder questionnaires, comparison to target population Administer a reduced assessment battery

More ideas on Fieldwork II can also be found in Phase 4 (Section 3.5.2).

3.1.7 Phase 0: Questionnaires

As described under Chapter 3.1.7 Phase 0: Questionnaires are a main instrument of HBM-Studies. They help to elucidate exposure pathways and provide information on specifics of sample taking. In the Planning Phase it has to be decided how much time shall be spent for answering the questionnaire (remind the participant burden!), in which way a main (basic) questionnaire shall be applied, e.g. in a face-to-face performance or self-administered (paper and pencil, Computer Assisted Investigation CAPI, or online). Also the dimension of a non-responder questionnaire has already be laid down for the ethics authority. Each applied instrument should be accompanied by a tailored questionnaire, e.g. for the urine sample it is important to know when the sample was taken,

when and what the last meals were, etc. Therefore the sampling questionnaire is necessary, it is a written record of every event that occurs during sampling and all sample-related parameters (date and time of collection, volume, length, colour, problems encountered, etc.) or any particular information necessary for the interpretation of the results and it is related to the moment of the sample collection. If a new questionnaire is going to be developed decisions on the way of validating it have to be made and small pilot studies have to be taken into account. In the frame of HBM4EU Task 7.3 takes the responsibility to develop several questionnaires e.g. a basic questionnaire to collect information on socio-demographic characteristics, lifestyle, specific questionnaires for first prioritised substances, sample specific questionnaires and satisfaction questionnaire for the first prioritised substances. The questionnaires will be provided in deliverable D7.3 Annex 2.1.

3.2 Phase 1: Preparatory Phase

After decisions have been taken in Phase 0, the Preparatory Phase (Phase 1) begins, i.e. all parameters which have been decided upon have to be prepared such enabling the start of the fieldwork. Most preparation is necessary on documents be it for communication issues, for fieldwork, for quality issues (SOPs) or for data management and the request for permissions. This Preparatory Phase can also take some months.

At the latest at the beginning of the Preparatory Phase decisions on the **responsibilities** for different parts and issues of the study conduct have to be fixed. Decisions on conducting a regional or national study mostly involve different organizational bodies. The **study owner**, as the body responsible for (financing) the study (i.e. a country, federal ministry or research institution), usually delegates the operational tasks to an **administrative body** (i.e. a federal, regional or local agency, or research institute). This administrative body, or in case a delegation is not necessary, the study owner directly, is responsible for the proper implementation of the study (directly or using subcontracts).

Implementing a study includes the organization and conduct of the study. It is therefore connected to the establishment of a **Survey Office** which functions as the central unit for conducting fieldwork and is responsible for managing recruitment and sampling of participants i.e. is responsible for general aspects, organizational background with long-term preparation. The Survey Office is mostly supported by **field staff** that takes charge of aspects happening at the sampling location which can be organized on short notice, i.e. is responsible for the direct interaction with the participants during the fieldwork. Due to this separation of duties, it is the duty of the Survey Office to take care of all issues of the Preparatory Phase.

Important tasks for the Survey Office in Phase 1 if a new study is planned are listed below. Additions for aligned studies may be necessary (see in brackets). Table 1 already provided an overview.

- Preparing/start preparing the Study Protocol, Fieldwork Manual and SOPs (aligned studies may need extensions)
- Developing and applying a concept for data management and authorization by data protection agencies (aligned studies may need extensions).
- Applying for authorization of the study by ethics committees (aligned studies may need extensions).
- Creating a database for the contact details, and a separate one for the questionnaire data and analytical results (aligned studies may need extensions).
- Preparing a protocol sheet to track the recruitment procedure (first personal contact until appointment is fixed).

- Ensuring the availability of all communication material, non-monetary incentives, a reception sheet for monetary incentives and all **questionnaires** in the main country language(s). Written materials should be translated into languages country inhabitants and main immigrant groups usually speak and be available in printed form as well as electronically (aligned studies may need extensions).
- New developed questionnaires for the first prioritised substances for HBM4EU have been developed by Task 7.3 and are provided in deliverable D7.3. Testing the translated questionnaires is in the responsibility of the Survey Office of each country (10 to 15 test interviews with volunteers need to be performed) (may also be necessary for aligned studies).

Following aspects have to be taken care of for the **biological samples /analytics**:

- Part of the communication material are also documents providing advice for the participants for storage and handling of the samples the participants have to take, these have to be prepared.
- Either contact a lab of the own institution or prepare documents to tender laboratories (may also be necessary for aligned studies). The intended limit of quantification of the selected biomarkers has to be taken into account.
- For HBM4EU project the samples have to be analysed in laboratories that achieved successful results in the HBM4EU ICI/EQUAS scheme for the corresponding biomarker.
- Sample traceability: Guarantee the unambiguous identification of the samples, aliquots and related documents. Check the quality of the labels employed and ensure that the ID code remains legible irrespective of the conditions (temperature, humidity, etc.) and that the label remain stuck to the tube, vessel or document (should already be tested for aligned studies).
- Prepare a sample reception protocol to be filled in by involved labs, necessary to control the integrity of the packaging and the conditions of the sample tubes and vessels
- Database of aliquots: Create a database including the sample ID code, aliquot ID code, sampling date, freezing date, type of sample, aliquots remaining after analysis, location in the bio bank, etc. (should already be present for aligned studies)

Time necessary for preparation shall not be underestimated as all parts of a study (data management, communication, fieldwork including recruitment and sampling, analytics) are complex issues –sometimes just realized while working on the details.

The Study Protocol provided here focuses on recruitment, sampling and fieldwork but gives short information on the other issues necessary for a proper study conduct. Within the HBM4EU programme this preparatory work is shared. Several working groups are involved as indicated in Table 12: e.g. Task 7.3 will prepare the questionnaires for upcoming studies, including a basic questionnaire, a sampling questionnaire as well as questionnaires to evaluate satisfaction and non-responders. Communication material as non-monetary incentives will be provided by Task 7.5. For Ethics and Data Protection matters, Task 1.5 will be involved and Data Management is handled by Work Package 10, analytics by WP9.

Table 12: Tasks of Phase 1 and respective main documents

Tasks of Phase 1	Respective main documents
Prepare a Study Protocol, start Fieldwork Manual	Deliverable 7.3 (Annex 1 and 2)
Prepare (and test) questionnaires & Interviewer Manual	Deliverable 7.3 (Annex 2.1)
Prepare analytics	Deliverable 7.3 (Task 7.3)
Prepare data management	Deliverable 10.1 (Task 10.1)
Prepare communication material	Deliverable 7.4 (Task 7.5)
Apply for authorisation (Ethics & data protection)	Deliverable 1.5 (Task 1.5)

3.3 Phase 2: Concretisation Phase

After careful planning in Phase 0 and preparation in Phase 1, Phase 2 comprises the concretisation of the work ahead, tasks are started to be turned into practice, e.g. material is bought or labs contracted. At this point, all prerequisites for the study, like ethics authorization and data protection issues are solved.

Table 1 already addressed the matters most important in this phase. Table 13 provides a more detailed overview. Responsible for the implementation of these tasks is the Survey Office.

Table 13: Overview of the tasks of the Concretisation Phase and needs for application

Concretisation phase	Apply for
Finalisation of the Fieldwork Manual with all SOP and questionnaires	New study / aligned study
Engage qualified interviewers/ fieldwork staff	New study / aligned study?
Organise and perform the training of the interviewers /fieldwork staff	New study / aligned study?
Buy material for the sampling of the matrix to be collected (sample vessels, aliquot tubes) and material for the field staff (laboratory equipment, office and dispatch material). If necessary, prepare the material for the sampling (clean with acid solution, label it, etc.). Also material for the transport of the samples to the laboratory or biobank have to be taken into account.	New study / aligned study
Fix relation to intended laboratories, sign contracts. Define the date and delivery format for the results: type of file, units, report about the internal quality controls applied, etc.	New study / aligned study?
Organise the incentives which have been selected for the participants (books, bags, etc. with study logo) and a reception sheet for monetary incentives	New study / aligned study?
Provide packing lists and prepared material for the field staff	New study / aligned study
Decision on exact start date and duration of the fieldwork	New study / aligned study
Schedule the visit of the sampling locations (e.g. cities) (provide a route plan)	New study / aligned study?

3.3.1 Phase 2: Fieldwork Manual and field staff

In order to ensure successful fieldwork, the finalisation of a detailed **Fieldwork Manual** has to be elaborated, the preparation of which already started in the Preparation Phase. A well-elaborated Fieldwork Manual is of the essence to cover the entire process of the fieldwork and answer possible questions. It can also be called operational manual and contains written information on all procedures, instructions and guidance for use by the personnel in the execution of their duties and blue prints for needed documents which were prepared in the Preparation Phase (see separate document 'Fieldwork Manual', Deliverable 7.3 Annex 2).

A careful selection process for the **field staff** has to be employed as a matter of quality assurance; individuals with experience in similar studies can be an asset. The field staff, especially interviewers for face-to-face interviews, are the direct contact persons for the participants, they "create" the quality of the collected data and samples. The number of persons engaged is in relation to the sampling points and number of households in that sampling point. Medical education is necessary if blood samples shall be taken. The field staff should be able to substitute each other in case of unforeseen absence.

Before the start of the study, the field staff needs to be trained. A training workshop has proven to be necessary. This workshop should not only explain details of the work flow (how to plan and conduct the interview, how to take samples, sample aliquoting, transport, sample reception, filling out all documents involved in the sampling procedure. etc.) but should also provide an overview on the study itself, its background, the background of the questions and specific topics. It is important that the entire field staff is given the same background and instructed in similar fashion (e.g. to read each question literally) to avoid bias (also see Deliverable 7.3 Annex 2.2.2 SOP 2: Quality Assurance for Recruitment and Fieldwork).

To ensure quality and comparability, a test run with voluntary participants should be considered. Interviewers should also answer the entire questionnaires and do the sampling themselves.

In case there are indications the conducted fieldwork does not comply with the required processes and documented Standard Operating Procedures, it might become necessary to organize a refresher course for the field staff.

Last but not least, Phase 2 also includes the creation of a detailed fieldwork schedule with start date, end date and route plans for the field staff.

3.3.2 Phase 2: Biological samples / Analytics

Organisation and control during the fieldwork: If it has been decided that the samples of the participants will be handled directly in the field, it might be necessary to have a minimum laboratory equipment, e.g. refrigerator, centrifuge, etc. and appropriate facilities to avoid the contamination of the samples. These devices have to be ordered in the Concretisation Phase. Also conditions for the conservation and transport of the samples during fieldwork have to be checked in advance to ensure its optimal conservation in order to avoid the loss of samples in the fieldwork. Furthermore, the packaging must fulfil the regulations (local and general) concerning the shipping of biological material. Material has to be ordered. If the transport will be done by couriers, the coverage of its service needs to be checked in advance to prevent loss of samples.

Pertaining to the organisation of the sampling and aliquoting a sample reception protocol has to be distributed. This protocol shall be applied during the reception of the samples arriving to the laboratory. This procedure should include the checking of different items to control the integrity of the packaging and the conditions of the sample tubes and vessels to identify any problem that can pose a risk for the quality of the sample. Any problem encountered should be recorded in a specific document (the sample reception registry). Samples regularly need to be checked against criteria for acceptance/rejection of samples when arriving to the laboratory.

One important part of HBM-studies is the analysis of the collected biological samples. In the Concretisation Phase the relation to the labs which shall analyse the samples has to be fixed, i.e. necessary tender processes finalised and contracts signed. It is also advisable to fix the date for reporting the results and clarify the format of the deliverable, e.g., the units, the format of electronic file, if the report will inform about the internal quality controls applied for the laboratory during the analysis, what happens if the results are not available at the delivery date, etc.

3.3.3 Phase 2: Incentives

A decision about which incentives to apply initially, will have been made at this point and they will be ready for use. However, the process of deciding which additional incentives, especially if they regard organizational aspects of the study, to apply, should remain flexible throughout the active phase and should be prepared to address any newly emerging barriers or needs as they evolve. If a decision towards incentives, e.g. monetary (vouchers) or small gifts, has been taken, these will have to be organized or bought in the Concretisation Phase. In case money is paid (e.g. reimbursement for time efforts and travel costs) receipt forms must be prepared to document payment. Frequently, these also involve the assessment of participant-sensitive information (e.g.,

social security number) which could pose a barrier that ought to be considered when preparing such incentives.

3.4 Phase 3: Starting Phase

After the preparation phase has been finished, Phase 3, the Starting Phase, begins. This is some weeks before the fieldwork in one sampling location starts and pertains all that is necessary to be able to visit participants or welcome them in an examination centre to take part in the study.

The Starting Phase includes several tasks for the Survey Office that mostly need to be done for new studies only (assuming that studies to be aligned have already begun).

3.4.1 Recruitment

The most important part of a study is the recruitment of participants which starts with organising and acquisition of participant addresses. Depending on the target population and the sampling frame that have been decided about in Phase 0 the addresses of potential participants can be drawn from various sources. A first step is to organise the addresses of potential participants e.g. from population registries, from patient files, or schools. This can be done some weeks in advance but it has to be paid attention to the possibility of changing addresses which increases with the timely distance between searching for addresses and sending individual invitations.

In order to perform a study that is representative of the target population, a random sample of that population should be drawn. If it is not possible to approach population registers other kind of registers could be approached. Telephone directories used to provide a complete picture of adults of a specific region and in some countries they still do.

Address holders (registries or institutions) have to be approached or in case this is not possible potential participants can be approached directly (like pregnant mothers in maternities). In any case emphasis should be put on a random sample as representative of the target population as possible (details see Deliverable 7.3 Annex 2.2.1 SOP 1: Selection of Participants and Recruitment). An overview is provided in Table 14.

Table 14: Phase 3 (Starting Phase): Obtaining addresses of potential participants

Target population	Sampling frame already decided in Phase 0	Address of first contact (whom to contact in Phase 3)
<i>General population separated for gender/age</i>	Population register (country, regional)	Holder of list: contacted via formal letter. Participants of ongoing studies: Study personnel (contacted via formal letter)
<i>Vulnerable population (pregnant, newborns, seniors etc.)</i>	Patient files, clinics, doctors	Confidant/ Head of institution (contacted via formal letter or personal visit)
<i>Selected occupational population</i>	Employment records, branch organisations	Head of organisation (contacted via formal letter or personal visit)
<i>Children, adolescents (different age groups)</i>	Kindergartens/day care centres, or their groups Schools, vocational schools, or classes	Head of institution (sometimes at first the education authority have to be contacted) (contacted via formal letter or personal visit)

After an address list of potential participants is obtained the completeness of the list has to be checked and safeguarded to be able to perform the selection procedure according to statistical routines taking care of the proper representativeness of the study.

The addresses are necessary in order to establish a first contact with potential participants via letter, call or personal visit.

3.4.2 Filling databases

For new studies, the databases set up in Phase 2 now have to be filled with these addresses of the potential participants and a study-specific ID-number for each potential participant has to be added, which serves for pseudonymisation of results. During this process and from here on out, data protection always has to be ensured.

3.4.3 Prepare fieldwork at sampling locations

Besides being prepared to contact participants, in the Starting Phase also preparations at the first sampling location (i.e. the region or city where the study will take place) are included; these have to be repeated in each sampling location participating in the study. E.g., if appropriate, rooms have to be acquired that serve as examination centres at the sampling locations as well as rooms for the field staff. This might also be necessary to do for aligned studies, depending on the initial study's characteristics. Examination centres can be schools, town halls, rooms in clinics or other premises. Most important is that they can be reached easily, preferably with public transport and that they serve the needs for the study (waiting room or reception, room for interviews, room for exercises, sanitary facilities, etc.).

3.4.4 Inform general public

At the same time, information of the general public about the study at the sampling location has to take place. This serves to raise awareness for increasing the participation rates (see Phase 0, Section 3.1.5, Table 9).

3.4.5 Inform the labs

Laboratories hired to analyse the biological samples have to be informed about the upcoming start of the fieldwork to prepare them to be ready to start the moment the first samples will reach them.

3.5 Phase 4: Fieldwork

As indicated in Table 1, Phase 4, the Fieldwork Phase, can in turn be split up into two phases. They differ in their way of involving the participants.

3.5.1 Phase 4: Fieldwork I

Fieldwork I revolves around the first contact with individual participants, their invitation and clarification of their inclusion, the fixing of an appointment for their personal involvement, as well as the provision of material to collect samples with.

Fieldwork I can also be described as recruitment on the individual level (whereas the word "recruitment" also includes recruitment on the general population level and therefore includes the contact to address holders etc. as mentioned above in Phase 3). In this Phase 4, Fieldwork I, the duties of the Survey Office include the preparation and sending of individualized communication material like a personal invitation including informed consent to potential participants.

The Survey Office will receive participants' answers and is in charge of the recruitment interview where it is checked whether inclusion criteria are met or the potential participant has to be excluded. Included participants will be send further material necessary for the study, e.g. material to collect samples (e.g. urine vessels) or self-administered questionnaires. Further duties are described in Table 15.

Table 15: Duties of the Survey Office during Fieldwork I

Fieldwork phase I	Apply for
Prepare and send individualized communication material including informed consent and a kind of reply card to potential participants	New study / aligned study?
Install a help-desk phone number for the participants	New study
Perform recruitment interview and check whether inclusion criteria are met or not	New study / aligned study?
Use the protocol sheet to track the recruitment procedure from the first personal contact until an appointment for individual participation has been fixed (<i>if appropriate</i>)	New study
Perform the non-responder interview via telephone if a potential participant refuses to participate	New study
Provide and fix appointments for the participation in interview/examination/sampling (<i>if appropriate</i>)	New study
Send material to collect samples (e. g. urine vessels) or self-administered questionnaires to the included participants (<i>if appropriate</i>) including storage and handling advice for the participants	New study / aligned study?
Provide the field staff with the participant addresses (<i>if appropriate</i>)	New study
Keep a thorough documentation of each decision, action, accomplishment and comments received from participants and staff (also in Fieldwork phase II)	New study / aligned study

In case the Survey Office is not able to reach all selected participants to ask them for their participation it is the duty of the field staff to contact potential participants when they arrive at the sampling location because for statistical reasons it is necessary to try very hard to reach each random selected participant (see Fieldwork II below).

3.5.2 Phase 4: Fieldwork II

Fieldwork II focuses on the involvement of the participants in the survey, mainly done by the field staff. It includes the interview or the self-administered questionnaire, the examination, taking of samples, provision of incentives and notification about the results. All preparations need to be finished: the core element of the study is starting.

3.5.2.1 Individual recruitment procedure

Figure 1 provides an overview of the recruitment procedure on the individual level. Starting from the participant address and the first official invitation, the figure shows how to continue in case of agreement, disagreement or no response from the participant up to the point in time when an appointment with a potential participant is fixed – turning the potential participant into an actual participant.

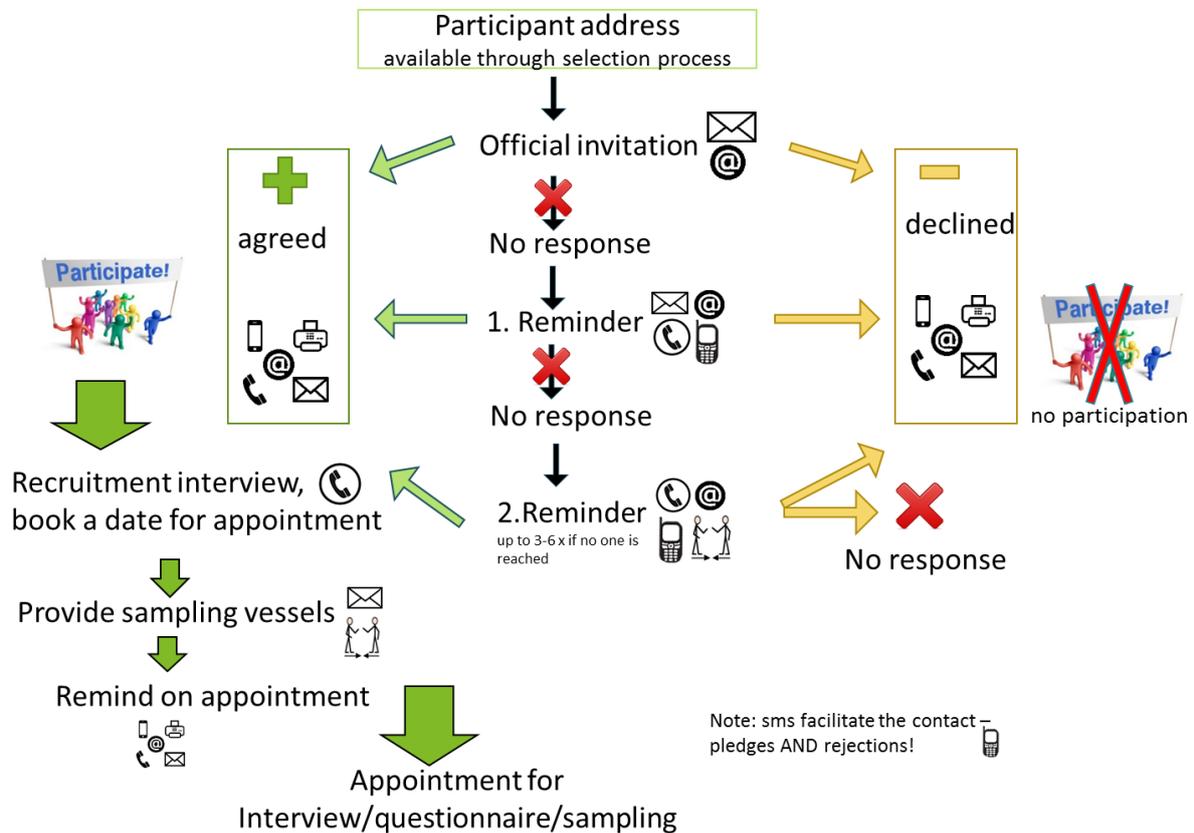


Figure 1: An overview and recommendations for individualized communication

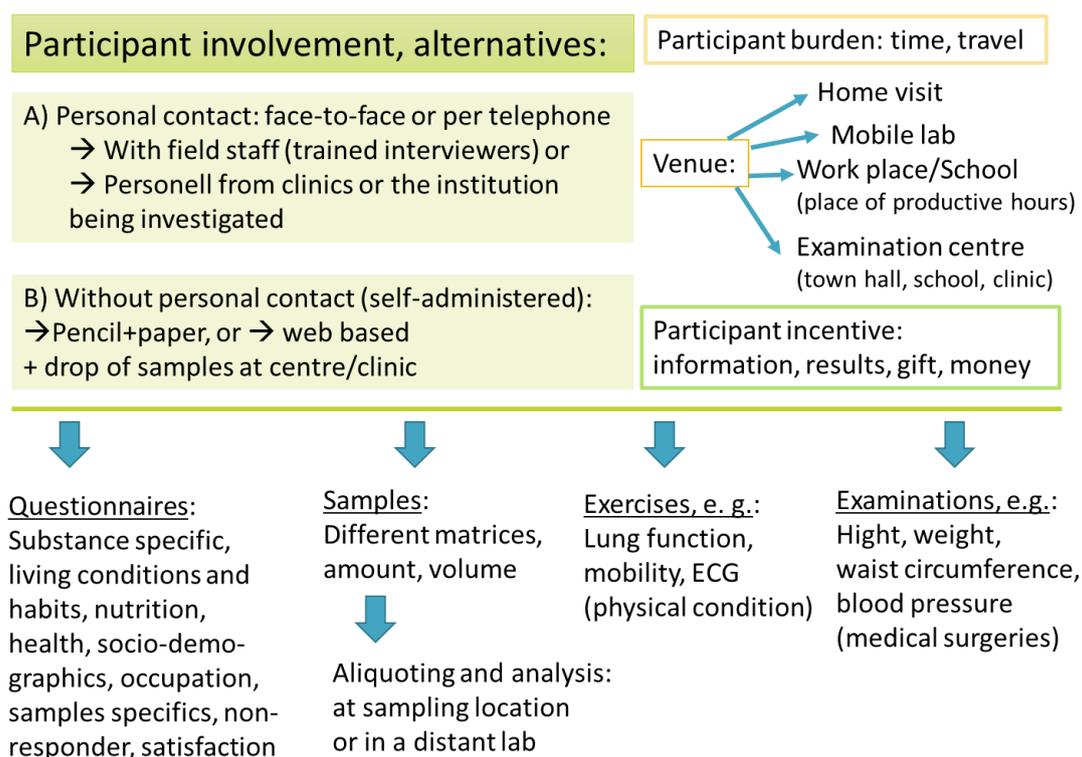
Lessons learnt from already conducted studies show that the first individualized invitation for the study should be send to the potential participants about three to four weeks in advance to the expected participation of the participant. This may lead to the 3-week-plan shown in Table 16.

Table 16: Example for approach to general population, starting 3 weeks prior to begin of study

Days	
1	Send official personalized invitation ✉️ @ (including the date for proposed appointment and a reply card)
2-9	Waiting for response
10	1. Reminder ✉️ @ 📞 📱
11-15	Waiting for response
16	2. Reminder @ 📞 📱 👤 👤
17-20	More reminders if necessary 👤 👤 (personal visit by the field staff)
21	Envisaged participation

*Note: Text messages facilitate the contact, for pledges **and** rejections!

Fieldwork II includes mainly the **duties of the field staff**, i.e. involving participants more directly in the study. Figure 2 shows some alternatives to do so (there detailed planning and preparation has already been done in Phases 0-3).

**Figure 2: Alternatives for participant involvement**

Participants can be involved through **personal contact** with the field staff. Maybe a first personal face-to-face contact can be necessary to ensure participation, particularly if other measures (letters, phone contacts from the survey office) did not succeed to enrol the potential participants (this first visit is part of Fieldwork I). Personal visits of the field staff at the home of the potential

participants (if not reached by phone) is the last possibility to ask potential participants for their participation.

An actual first face-to-face contact can be the guided interview either through trained interviewers or personnel from the institution that is involved in the study (e.g. personnel from clinics) with the traditional pen and paper or a Computer-Assisted-Personal-Interview (CAPI).

Participant involvement can also be achieved without personal face-to-face contact. This includes a self-administered questionnaire, e.g. sent by mail (pen and paper) but also web-based applications. Self-administered participant involvement will include some form of dropping of samples at a centre or clinic or a transport by mail while it is most important to provide distinct storage and handling advice for the participants.

Whether the **venue** of the direct involvement is at home during a home visit, at a place of productive hours (work place or kindergarten) or at an examination centre (town hall, school, clinic), or, less common, in a mobile lab, the participants will always be burdened in some form (time spent and travel effort). Therefore it is advisable to offer alternative possibilities, e.g. participants can choose to be visited at home or visit an examination centre near to their home to take part in the study.

In order to compensate for their burden, participants can receive **incentives**. These incentives (to be decided already in Phase 0) are often information, personal results or money, but can also be goodies (e.g. toys for children). For an overview, see Table 11. Use of incentives should be discussed and agreed upon by a (national) ethics committee. It has been shown that small (monetary) incentives provided before the start (together with the invitation) increase the participation rate.

Depending on the study design, the **direct involvement of participants** requires to provide samples, partake in exercises or examinations and complete questionnaires. For the Survey Office or field staff this often means several study-specific details have to be considered when planning the venue of the participant involvement. **Samples** can include different matrices, can vary in amount or volume and need handling (aliquoting, transport and analysis), either collected by trained staff or by the participants themselves. If exercises to determine the physical condition are necessary, e.g. to test lung function, mobility or to record an ECG, the required measuring instruments have to be available (ordered already in Phase 2). Other examinations, e.g. for height, weight, waist circumference and blood pressure, might be possible to perform in a different/second venue and might need different skilled field staff.

Questionnaires, self-administered or guided by an interviewer, are an essential part of many studies. While there are several options when bringing a participant into contact with a questionnaire (self-administered or completed during a home visit or phone interview), it usually takes quite some time to fill out and is hence likely to heighten the participant burden. Questionnaires can be substance or sample specific, cover living conditions and habits, nutrition, health, socio-demographics, occupation or participant-impression related, like non-responder questionnaires and satisfaction questionnaires.

3.5.2.2 Preparations for participant involvement

Fieldwork II, the direct involvement of the participants requires careful planning to ensure **proper study conduct**. This planning concerns all phases of the involvement. The field staff is required to take care of several matters. The following steps are mandatory for new studies with personal contact to the participants and facultative for aligned studies.

- ▶ **Prior to the visit** of the sampling location, the field staff (interviewer) needs to stock up the necessary material for the visit of the sampling location (procured by the Survey Office in Phase 2), to be prepared to stock up the materials before each single participant visit. The field staff also receives from the Survey Office addresses of the participants for the sample location to be visited. In case a stay overnight is necessary, an accommodation should be rented (already in Phase 3).
- ▶ **Upon arrival at the sampling location**, the accommodation or examination centre has to be furnished with study equipment and devices.
At this point in time, the field staff also tries to contact one last time potential participants that have not been reached so far by the Survey Office.
- ▶ **The day before visiting the participants** in their home or at the examination centre, the equipment necessary for the upcoming visit (such as interviewer identity card, papers, laptop, additional sampling vessels, incentives etc.) has to undergo an integrity check. Maintenance and record of study devices (e.g. refrigerator for short-term storage, pipettes for aliquoting) should be performed every day.
- ▶ **During the visit**, special care has to be taken if the participant involvement takes place in the participants' homes. Respect for the residents and close observation of household etiquette is strongly recommended to avoid negative effects on participation rates.
Ahead of any other actions taken, the interviewer checks and accepts the declaration of informed consent from the participant. Afterwards, the questionnaire can be filled out, measurements and samples taken. There should always be a certain flexibility in carrying out these tasks to adapt to the most convenient order for the participant.
The visit needs to be well documented with details concerning duration, completion, handovers and consent.
- ▶ **After the visit to the participant**, be it in his or her home or at an examination centre, the samples need to be processed. Transport or shipping to the accommodation or Survey Office or even directly to the laboratory needs to be conducted according to shipping protocols.
An additional visit at the next few days should be offered to the participant if not all parts of the study were completed at the first visit.
- ▶ **Once all visits at a sampling location have been completed**, location reports (numbers and potential issues) are to be sent to the Survey Office. In case samples have not yet been shipped, they should be sent out to the Survey Office or directly to the laboratories at this point.

3.5.3 Phase 4: Biological samples / Analytics

During Fieldwork II biological samples are received from the participants. Either they have to be prepared for further processing (aliquoting) or for shipment to the analysing laboratories which have been (sub-) contracted. Shipment has to follow Standard Operating Procedures (see also Deliverable 7.2 Annex 1 SOP: Sample Exchange on a pan-European level to be used in the HBM4EU initiative) to warrant high quality of samples.

3.5.4 Phase 4: Questionnaires

Application of questionnaires is a duty of Phase 4. As pointed out on the preceding page and under Phase 0, there are different ways to involve participants with questionnaires. In most studies different kind of questionnaires are applied in different ways, e.g. a face-to-face interview for the large basic questionnaire which covers nearly all exposure pathways and also asks general questions on socio-economic variables. Sample specific questionnaires are often self-administered (and checked by an interviewer when he accepts the samples). Health questionnaires sometimes are sent by mail or via an online tool for self-administered use. To cover exposure pathways of the first prioritized substances in the frame of HBM4EU a set of questionnaires is developed by Task 7.3. The basic questionnaire is attached to the deliverable D 7.3, there also information on

necessary translation and an **Interviewer Manual** explaining the background of the questions can be found. If, for aligned studies, only some of the provided questions shall be used a logic sequence of the questions has to be warranted.

During **Fieldwork II** the **Survey Office** has several **duties** to fulfil, too.

These duties include the general supervision of the fieldwork (performed by interviewers or field staff, see also Deliverable 7.3 Annex 2.2.2 SOP 2: Quality Assurance for Recruitment and Fieldwork) and to provide help and advice if necessary, but also the conduct of internal quality control for fieldwork. Evaluation should be closely monitored by the Survey Office to check for signs of differential participation and to compare with the target population. It is further required to organize and conduct additional trainings for the field staff.

Additional training of field staff as well as a report covering experiences and lessons learnt to the responsible unit is required for both new studies and aligned studies.

Only for new studies (as in an ongoing study, data protection should already be included), the Survey Office needs to safeguard data protection when keeping the participants' addresses and it is also required to provide the data base filled with the questionnaire data (participants' answers) to the data management unit for **evaluation of study results**.

3.6 Subsequent steps

Shortly after the fieldwork is finished in one sampling location the procedure starts again for a next sampling location. In parallel, the laboratories can start analysing samples which is a prerequisite for reporting the results back to the participants (in which way this will be done had already to be described for the ethics authorization). But before results can be reported the data of the questionnaires and the samples has to be checked. After the fieldwork is completed in all sampling locations results of the different instruments have to be merged, checked and analysed with statistical software. Only then advice for the (general) public and politics can be provided.

4 Occupational Exposure

4.1 Integration of occupational exposure in general HBM-surveys

Information on occupational exposure may be obtained in general HBM-studies (or other studies such as cohort studies). In a study targeted towards the general population information on occupational title and type of work may be obtained through questionnaires or registers with information on occupation. Exposure assessment can be conducted either using a Job-exposure matrix (JEM) or through the biomonitoring sample (for exposures where this is possible). Table 17 lists advantages and disadvantages of integrating occupational aspects in general population studies or performing single studies on workers. An advantage of this approach is that information on a large number of potential confounders may be available and that information on exposure is obtained for individuals with a variety of occupations. A disadvantage is that it is often difficult to evaluate exposure based on job title (which will lead to exposure misclassification). Moreover a large sample size is needed to ensure a sufficient number of individuals in each occupation, in particular for more uncommon occupations.

Table 17: Integration of occupational aspects in surveys

Target population (study pop.)	Information on occupational exposures	Pros	Cons
<i>General population study or large cohort</i>	Add questions on occupation (and type of work) or link to register with information on occupation	Detailed information on potential confounders Information on exposure also in individuals with other occupations Larger exposure gradient when also general population with (nearly) zero exposure is included	Difficult to evaluate exposure based on job title (exposure misclassification) Risk of few individuals in each occupation
<i>Employees in a specific occupation</i>	Occupational setting with the defined exposure (direct measure of exposure possible)	Possibility to have more specific information on occupational exposure Larger number of individuals with the exposure of interest	No information on exposure in individuals with other occupations or the general population

4.2 Studies in occupational settings

An alternative approach to obtain information on occupational exposure is to target employees in a specific occupation and/or occupational setting. This may enable direct measure of individual exposure, which generally provides an accurate estimate of the actual situation, provided that the measurements are performed under normal working conditions and reliable methods and monitors are utilized in a suitable manner. An advantage with this approach is the possibility to have more specific information on occupational exposure and a larger number of individuals with the exposure of interest compared to HBM-studies of the general population. A disadvantage is that there is no information on exposure in individuals with other occupations or in the general population (see Table 17). The special requirements to the organisation of fieldwork in occupational settings are described in Table 18 (see also Table 1 for further Phases).

Table 18: Organisation of fieldwork in occupational settings

Characteristics	
<i>0 – Planning Phase</i>	Decide on study design , identify target population (i.e. occupational setting), choose participant selection procedure, recruitment procedures and contact procedures
	Define inclusion and exclusion criteria , and encouragement of participants
	Identify suitable occupational setting and/or workers (through trade organisations, unions, or registers with information on occupation)
	Decide on samples (which samples, selection of matrices/biomarkers, time for sampling, amount, type of test tubes etc.)
	Contact employer and possible also unions and/or trade organisation
	For Phases 1 to 4, please refer to Table 1.
<i>Attention</i>	<p>Other details to keep in mind when organising fieldwork in occupational settings:</p> <p>Samples may be collected at the work place, in the home or at study centre depending on the type of biological samples (and additional data) collected and the work environment (it may not be possible to collect samples at work in all occupational settings). Coordination among those responsible for health-care at the industry/company/workplace should be considered.</p>

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Contract No. 733032 HBM4EU

Annex 2

Fieldwork Manual Template

WP7

Task 7.2

D 7.3

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Authors and Acknowledgement

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This document has been developed by Ulrike Fiddicke and Kim Pack from the German Environment Agency (UBA).

This Fieldwork Manual Template is based on and interconnected with the work done for Deliverable 7.3 and its Annex 1, the Concept for a Study Protocol. We would like to thank all authors mentioned in those documents for their input.

This document has been created for the HBM4EU project. HBM4EU has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733032.

1 Fieldwork Manual

1.1 Use and Objectives

Within a study, the Fieldwork Manual is the document to refer to during day-to-day business and also for the training of field staff (e.g. interviewers). It includes a detailed description of all steps of fieldwork and provides guidelines, checklists and instructions as well as Standard Operating Procedures (SOPs) to harmonise and facilitate the work of the field staff. It essentially covers all aspects necessary for the conduct of the study as far as they touch the direct involvement of the participants but also informs about the general objectives and procedures to enable the involvement of participants and to collect data and samples of high quality.

As HBM4EU is laid out to include several countries, it is important to note that every country has to develop its own Fieldwork Manual on the basis of the information provided with the documents of HBM4EU work packages. In some countries, adaptations might be necessary in order to account for national specifics, e.g. in some countries it is not allowed to distribute incentives to compensate the participants' burden, so the section on incentives has to be revised according to the national conditions.

However, adaptations should be kept to a minimum as the aim of HBM4EU is to harmonise the fieldwork procedures between countries to the greatest extent possible. All versions will be prepared in English, and have to be translated and adapted to national language(s).

The national Survey Office is in charge of preparing the Fieldwork Manual. It should start preparations at the very beginning of the study but updating whenever decisions have been taken is necessary up to the date the field staff shall be trained (and partly also thereafter). As it serves as a handbook to the study, everyone involved in the study (staff of the survey office, fieldwork team, data management team, etc.) should receive their own edition and everyone involved is responsible for pointing out need for updating to the Survey Office.

1.2 Structure

The idea of the Fieldwork Manual is to deliver a structured composition of the documents most important to the study. It essentially provides a handbook that collates both an in-depth description of how the study is planned out as well as all information necessary for conducting the fieldwork, such as master copies, checklists and questionnaires.

For practical reasons the Fieldwork Manual is structured in two main sections. Section I provides mainly detailed information on the respective study concerning its background and concrete details on ethics, data management and all fieldwork procedures etc. – as elaborated when preparing the Study Protocol but providing sophisticated details to enable the exact repeat of all procedures.

Section I can be structured identically to the Study Protocol (e.g. provided in the Concept for a Study Protocol, Table 4: Topics to be decided in Phase 0 of a study). For the template provided here we chose a slightly different structure to highlight that the focus of the Fieldwork Manual is providing information and documents for the field staff.

The second section (Section II) provides master copies, check lists, questionnaires and detailed SOPs for the procedures mentioned in Section I.

Following table gives an overview of a possible structure of a Fieldwork Manual.

Table 1: Overview of the contents of the Fieldwork Manual

Section I: Basic content of the Fieldwork Manual
1. Background and Benefits
1.1. Background of the study in the scope of HBM4EU
1.2. Objectives
1.3. Thematic Areas
1.4. Benefits for the individual participant
1.5. Benefits for the Public Health Service
1.6. Benefits for research
2. Study design, target population
2.1. Selection, sampling frame, recruitment
2.2. Inclusion and exclusion criteria
2.3. Definition of a case
3. Ethics
3.1. Information
3.2. Informed Consent
3.3. Revocation of participation and deletion of data
3.4. Data Protection
4. Project management and training
4.1. Responsibilities
4.2. Selection and training of field staff
5. Fieldwork
5.1. Time schedule for fieldwork and routes
5.2. Survey methods and instruments, e.g. all questionnaires and samples (types and handling of)
5.3. Plan of procedures for fieldwork, including all communication material, all details of involvement of the participants and provision of incentives
5.4. Quality assurance of fieldwork (training of field staff, field visits, quality assurance of sample handling)
6. Communication
6.1. Public relations
6.2. Activities to raise participation (FAQs, additional incentives)
6.3. Reporting results to participants
7. Data management
7.1. Databank for management and addresses
7.2. Data management system
7.3. Quality assurance of data handling and check
Section II: Annex to the Fieldwork Manual
(including check lists, master copies, pre-formulated letters, questionnaires, SOPs, etc. corresponding to the themes of Section I)

To give an example, the two sections of the Fieldwork Manual are briefly described below. Changes and adaptations for each single study are necessary as already indicated above. A more detailed description is offered in Chapter 2.

1.2.1 Section I: Basic content

The first section of the Fieldwork Manual can be structured e.g. in 7 main points that comprise the essential topics to address when conducting fieldwork (see Table 1 above).

The first topic (Background and Benefits) gives an overview of the study in the scope of the HBM4EU programme, provides details on the objectives and benefits on different levels (individual, public health and research) and elaborates on the thematic areas covered within the study.

Point 2 provides details on the design of the actual study, the target population, and the recruitment of individuals to achieve the desired amount of participants. Inclusion and exclusion criteria as well as the definition of a case, i.e. which data needs to be collected from a participant to involve him or her in the final data file, are to be described in detail here.

Ethics requirements are of utmost importance and an ethics approval is the essential prerequisite for a study including the collection of human data and samples. Therefore, it is appropriate to address these issues in a separate point (point 3). It includes detailed information on how (potential) participants are informed about the study, asked for informed consent, how they can revoke from the participation and if this has implications on them. Measures that have been taken to ensure data protection and accordance with ethics requirements are also described. The approvals of ethics and data protection authorities are mentioned.

The HBM4EU deliverables D1.5 'Legal and Ethics Policy paper' and D10.1 'Data Management Plan' including its annex should be read carefully and taken into account for point 3.

Before details of fieldwork are described, the management of the study is laid down under point 4 to inform about responsibilities for the different tasks. This is especially important if parts of study conduct are subcontracted. It also includes the responsibility and timing of training for the field staff.

The time schedule for fieldwork and routes, survey methods and all instruments (like questionnaires and samples) used as well as a detailed plan of procedure and information on quality assurance are elaborated on under point 5, Fieldwork. Single steps from first contact to fixing an appointment with the participant including all communication material, all details of involvement of the participants including e.g. furnishing of examination centres, provision of incentives and documentation of procedures like questionnaires and sampling are described in single sub-chapters.

Communication with the public (e.g. actions necessary in the different sampling locations) as well as special communication measures to raise the participation rate are reflected under point 6. These can be additional incentives or FAQ-list providing short arguments for participation. Data management including the databank for addresses and a data management system are described under point 7.

Quality assurance can be described in a separate point or detailed under the specific points.

1.2.2 Section II (Annex)

Section II of the Fieldwork Manual can also be called “Annex”. It is foreseen to include templates, master copies, SOPs, check lists and other material created for the conduction of the fieldwork for a daily use. These documents will be elaborated in the process of creating the Fieldwork Manual.

The documents sorted in the Annex simplify the standardization of all processes, e.g. the contact with (potential) participants or the actions the field staff has to take.

Following, some examples for Annex documents are presented:

- ▶ Approval of the ethics committee and the data protection authority
- ▶ Sheet indicating the duration of the fieldwork
- ▶ All communication material for the participants (invitation, information leaflet, reply card, reminder, informed consent, letter of thanks, results letter, incentives)
- ▶ Questionnaires –recruitment (inclusion/exclusion criteria)- basic, sample specific, satisfaction, non-responder (paper version in case the electronic version breaks down), Interviewer Manual with background information to the questions
- ▶ Drawing and handling of samples (for the participants and the field staff)
- ▶ SOPs for: - participant selection and recruitment; - fieldwork and quality assurance, sample reception and registration, sample handling, packing and shipment
- ▶ Routine procedures for fieldwork including a detailed process description, check lists for preparing the visit of the participants (at their home or at an examination centre).

2 Template Fieldwork Manual, Section I: Basic content

For each study, a Fieldwork Manual should be developed. The more detailed it is the more it serves the identical repeat of all processes of the study which contributes greatly to the high survey quality necessary for reliable data.

Provided herewith is a short description (partly bullet points) of what could be written in the chapters of Section I of a Fieldwork Manual. The documents for the Annex (Section II) result directly from the described chapters.

2.1 Background and Benefits

In this chapter, the focus should be on briefly introducing the study. This includes explaining what it has to offer in terms of aims and thematic areas, but should also elaborate on how and why this particular study was set up and how it relates to the overall HBM4EU objectives.

In the following chapters some examples are provided in bullet points and have to be elaborated appropriately for each study.

2.1.1 Background of the study in the scope of HBM4EU

- ▶ history of the countries studies in which this one is embedded
- ▶ relation to HBM4EU
- ▶ design and scope, etc.

2.1.2 Objectives

The study has the objective of providing current population representative data on the environmental pollution of people in the country.

The current data collected in the study also serves for:

- ▶ the identification and quantification of pollution sources and paths,
- ▶ as the basis for the derivation of reference values about the burden of the population to environmental pollutants, which then form the basis for a nationwide uniform assessment and will also be used as a European scale by EU-wide studies,
- ▶ the depiction of temporal trends in the burden,
- ▶ the identification of especially burdened groups,
- ▶ the examination of possible influences of particular environmental factors on the health situation,
- ▶ the evaluation of prevention, intervention and minimisation strategies within the scope of health and environmental measures.

2.1.3 Thematic Areas

The study program comprises the following components:

A) Human biomonitoring (HBM) on all participants:

- ▶ Whole blood, serum, plasma
- ▶ Morning urine samples (total amount of urine that is discharged in the morning); sampling is carried out by the participants themselves.

B) Interview-monitoring with all participants (face-to-face interviews, questionnaires for self-completion)

- ▶ The personal and written questioning includes standardised questions for detecting potential burden pathways for interpretation of the measurement results and of exposure-relevant behavioural patterns. Further, topic constellations such as environmental justice and environmental health problems are taken into consideration.

2.1.4 Benefits for the individual participant

- ▶ The analyses performed are, in some cases, very cost-intensive and are not a part of the normal analysis program which is offered by private practitioners.
- ▶ The study provides valuable information about their personal environmental exposure and their potential risks and information about how to reduce the pollution burdens.
- ▶ Participants receive, if they so desire, an environmental-medicinal evaluation of the measurement values
- ▶ The participants contribute significantly to a clarification of the individual-related environmental pollution of the population of the country and thus personally make an important contribution to research in the fields of environment and health and in health and exposure monitoring.

2.1.5 Benefits for the Public Health Service

- ▶ Results deliver a reliable assessment of the actual exposure situation for people in the country and enable federally uniform ratings of pollution burdens.
- ▶ The derived risk mitigation measures and information benefit the general population.
- ▶ Reference values for the corporal pollution burden of the general public (overall and stratified by age groups) are derived, indispensable for the assessment of individual situations and in the classification of results from local and time-limited environmental health studies.

2.1.6 Benefits for research

- ▶ The study will provide first insights into toxicological or health important substances to which the population may be increasingly exposed.
- ▶ The study updated essential basic data for estimation of the environmental pollutant exposure of people in the country.
- ▶ The data obtained will support future environmental-epidemiological studies and reinforce the scientific basis of governmental risk assessment.
- ▶ The data will be made available to the public and interested scientists as a "public use file".
- ▶ These analyses are an important first step to the generation of new hypotheses in environmental-related health protection and for prioritising research questions in longitudinal studies.

2.1.7 Other benefits

- ▶ There can also be benefits for institutions beyond the public health services. Other institutions with a focus on chemical regulations, risk assessment, environmental safety and/or food safety could potentially also use data or research conclusions from the study for their tasks.

2.2 Study design, target population

The design of the study and the rationale behind choosing this design should be explained in this paragraph taking the target population and aims of the study into account.

2.2.1 Selection, sampling frame, recruitment

A general overview of the sampling frame (i.e. the list of the target population units from which the sample is drawn) and the envisaged sample size is provided here, and how a random sample will be achieved. For example, a description is provided of the procedures to select 150 males and 150 females between 20-40 years who are envisaged to participate in a pre-selected geographical area. Therefore regional population registers will be approached to provide a list of adults of the selected age-group. The recruitment procedure through the approach via registries is described and additionally how the participants are approached individually (Fieldwork I).

2.2.2 Inclusion and exclusion criteria

This paragraph elaborates briefly on inclusion and exclusion criteria for the participants, e.g. exclusion of hospitalized individuals. It is useful to list these criteria separately to avoid misunderstanding during the recruitment process.

2.2.3 Definition of eligibility

Here it should be defined what data and samples collected are required in order to count a singular participant as eligible for the study case.

2.3 Ethics

In advance to setting up this section concerning ethics, it is required to consider the following HBM4EU ethics documents:

- ▶ D1.5 Legal and Ethics Policy Paper,
- ▶ D17.1 – D17.6 Ethic requirements (see Grant Agreement number 733032; page 111 of 128),
- ▶ First, second and following Ethics reports (see internal webpage work package folder/scientific and administrative management/WP1).

Task 7.5 has developed a template for the informed consent (see Deliverable 7.4).

2.3.1 Information

A short description is offered how participants are informed about the study and its background and objectives, e.g. when they are informed about the study, which (written?) material is provided to enable an informed consent.

This paragraph further includes the addressee of the application of the ethical approval for the study, the date of approval as well as a short description of the content concerning the reporting of results to the participants.

2.3.2 Informed Consent

A more detailed description of the declaration of informed consent for study participation is given, when it is provided, what it consists of, who (e.g. parents or children?) has to sign it. It is important that the participants also consent to that information and that samples are sent to other countries (at least within the EU). This often has to be stated separately.

2.3.3 Revocation of participation and deletion of data

Describe here how participants are informed how they can revoke their participation (complete or partial revocation of participation) and how and which steps need to be taken if such a revocation arrives to the field staff or Survey Office also concerning the deletion of addresses and already collected data. Also a hint to a respective SOP is advisable.

2.3.4 Data Protection

This section elaborates on details regarding data protection such as the addressee of the data protection concept for the study and the date of approval. In short, it should be described how participants were informed about data protection and the main statements. If applicable also describe how subcontractors are dealt with.

2.4 Project management and training

2.4.1 Responsibilities

It is essential to note down the different responsibilities and the names of the involved persons for the management of the different study parts, especially if a study is run by different partner institutions.

2.4.2 Involved personnel, their tasks and training

It is also recommended to describe in detail who is responsible for which single task, to warrant that all responsibilities are laid down. Expertise and criteria for hiring field staff shall be listed and information on training activities provided.

2.5 Fieldwork

2.5.1 Time schedule for fieldwork and routes

In order to provide a precise overview, the total runtime as well as the dates of beginning and end of the fieldwork phase should be named in this section. If there is no defined end date set, an estimation is also sufficient.

Further, it is recommended to list here the time planned in per sampling location.

For people of all age groups, but especially school children, holidays and vacations need to be considered when setting up a time plan. Possible seasonal differences should be balanced out within the time schedule for fieldwork.

2.5.2 Survey methods and instruments, questionnaires and samples

This section goes into detail regarding methods and instruments used to collect data.

If one or more questionnaire is planned to be used, the questionnaire(s) and all its parts and possible annexes are described and explained here. This includes the description of the format (self-administered, CAPI, etc.) and the explanation of the content as well as the most important points regarding handling of the questionnaire done by the interviewer. Additional questionnaires such as satisfaction questionnaires are also elaborated on under this headline.

Further, this section includes a description of all sample types (e. g. urine, blood, drinking water, etc.) taken and gives a rough introduction on how they are taken. Additionally it informs about the further processing of all samples collected, how field staff has to handle them e.g. how they are transported to the lab or another place for storage, etc.

2.5.3 Plan of procedures for fieldwork

The plan of procedures is foreseen to describe in detail every step taken starting with the contact to the participants up until the samples are handed over or send off for analysis. If fieldwork comprises many parts providing a flowchart may facilitate the overview. This allows for an in-depth insight in every step and can often not only promote the comparability within the fieldwork staff but also answer questions arising at the sampling location. It also addresses the incentives provided to the participant directly after being involved in the study.

Such a process could be described with the following chapters:

- 1) Contact phase, including recruitment of individual participants and transmission of address and contact data, the communication material for the participants (invitation, reply card, reminder (letter and/or call), Appointment confirmation and despatch of sample materials), (Fieldwork I), Procedure with foreign-language participants, contact by the interviewer at the sampling location

- 2) Prior to the sampling location visit: description of all what has to be done prior to the visit of the location (see Concretisation Phase of the study protocol)
- 3) Arrival at the location: description of all what has to be done by the field staff when they arrive at the sampling location
- 4) Before home visits: description of all what has to be done by the field staff the day before the visit of the participant, e.g. a phone call to remember on the visit and preparation of all that is necessary for that visit
- 5) During home visits: Description of the whole procedure of the visit of the participant home (or at an examination centre), including acceptance of the informed consent, the interview, the sampling, the handing over of incentives
- 6) After the home visit: description of what has to be done when the visit is finished, like sample transport, transmission of data and return of material that can be reused.

2.5.4 Quality assurance of fieldwork

To assure the quality, systematic observations and assessment if quality standards are upheld can be put into place. An independent assessment of the measures taken for quality assurance shall also be set up. It is highly recommended to keep in mind the guidelines for good epidemiological practice (https://dgepi.de/fileadmin/pdf/GEP_LL_english_f.pdf). Additional information provides SOP 2 Quality Assurance (QA) for Recruitment and Fieldwork (see Deliverable 7.3 Annex .2.2.2)

In here, it is further described how fieldwork is quality assured.

- ▶ Will there be field visits from study-internal or external personnel?
- ▶ Is extra training of the field staff foreseen, what can be a reason for extra training?
- ▶ How is the quality of the samples assured?
 - Frequency of temperature control,
 - Check lists for sample handling.

2.6 Communication

2.6.1 Public relations

Describe here the strategy for public relation and information of the general public in order to communicate the aims and potential output of the study. Describe the aims of these activities and the organisational responsibilities for these activities. Activities could be:

- ▶ Publication and continuous updating of a website informing about the survey
- ▶ Establishment of a hotline for questions from both participants and the public
- ▶ Information of local authorities about the conduct of the study in their area
- ▶ Documentation of (local) publications about the study
- ▶ Interviews with different types of media (press, radio, TV, etc.)
- ▶ Tweets and posts on social media such as Twitter and Facebook
- ▶ Scientific publications and representation at conferences

2.6.2 Activities to raise participation

A high participation rate is of utmost importance for representative studies, therefore the field staff has to be able to communicate the objectives of the study to best inform potential participants.

Providing answers to frequently asked questions is a widely used communication tool. Answers should be provided already at the start of the study e.g. for the study web page but can also assist the argumentation for the interviewers.

Examples for such questions can be:

- ▶ 'I don't have time to participate.'
- ▶ 'What is the purpose of this survey?'

- ▶ 'Why did you choose me?'
- ▶ 'What do I get from participating?'
- ▶ 'How much time do I have to spend on this?'
- ▶ 'What happens to my data?'
- ▶ Will I get my individual results – and when?

A frequently used measure to raise participation is the provision of incentives. Which incentives will be offered to potential participants, when and how should be described here.

2.6.3 Reporting results to participants

This section is likely to vary between countries as it is closely interlinked with the ethics approval. Results can be reported as a whole or in parts, they can include commentary and explanations or they can be blank and other fulfil requirements that can be different across country borders.

Here, the process of reporting results to the participants should be elaborated on, including how they are informed (in person, via letter, via phone call, etc.) and what they are presented with.

2.7 Data management

All information and templates regarding HBM4EU Data Management should be considered when setting up this section. They are available via <https://www.hbm4eu.eu/data-management/>. The helpdesk on data management is available to support and advice you in data management related tasks of WP10 (internal webpage: https://www.hbm4eu.eu/privatehelp-desks_trashedwp10-help-desk/).

2.7.1 Databank for management and addresses

For the control and documentation of all steps of the fieldwork a database should be developed. Its use and functionalities and the rights to access it should shortly be described here.

2.7.2 Data management system

If a study consists of different parts which are in the responsibility of different partners it may be advisable to establish a data management system, this should be described here as well as the main functionalities and access rights. Timing of data transfer between the partners should also be described here.

2.7.3 Quality assurance of data handling and check

Without being thoroughly checked, no data can be reported to anyone or merged with other data. Whenever data is collected it has to be cross-checked for correctness and validity. This section should inform about measures taken to assure data quality.



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Annex 2.1

Documents for Interviews

WP7

Task 7.2

D 7.3



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Contract No. 733032 HBM4EU

Annex 2.1.1

Basic questionnaire for 1st priority substances

WP 7

Task 7.3

D 7.3

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1 Authors and Acknowledgements

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Co-authors

Co-authors are members of the task 7.3. Below we list them individually by section of contribution, name, and short name of partner institution.

1.- Elaboration of the Basic Questionnaire

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1. Elaboration of Specific questionnaires on 1st priority substances:

1st priority substances	Name (Partner)
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This document has been created for the HBM4EU project. HBM4EU has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733032.

2 Introduction and Aims

The elaboration of the questionnaire has been based on existing experience and knowledge of all members of the task 7.3. First a checklist was elaborated to identify groups or blocks of questions worth being included in the questionnaire. After discussions in Task 7.3 major topics were identified: I) sociodemographic characteristics; II) exposures to a range of compounds in the residential environment; III) dietary habits; IV) lifestyles; V) occupational exposures; VI) health status. Additionally, an online systematic search was conducted to identify questionnaires already used in relevant human biomonitoring studies carried out in other countries around the world (Canada, Czech Republic, Denmark, France Germany, Italy, Israel, Korea, Russia, Spain and USA), as well as countries participating in the DEMOCOPHES project. Questionnaires identified were evaluated using an evaluation sheet, based on an extension of the previous checklist to identify relevant questions that should be included in the basic questionnaire.

The resulting basic questionnaire takes into consideration questions identified through the evaluation of questionnaires and other questions proposed by partners according to their relevance for the study covering the first priority substances.

The basic questionnaire is structured as follows:

- a) Sociodemographic characteristics.
- b) Residential environment and home exposures
- c) Dietary habits
- d) Lifestyles
- e) Occupational exposures
- f) Health status

The basic questionnaire aims to collect individual information in a standardized way from each participant, as this will enable to obtain comparable results across countries involved in the HBM4EU study.

This questionnaire has been designed to collect all the necessary information concerning individual characteristics of the participants and on different sources and routes of exposure to 1st-priority substances selected for study (Phthalates/DINCH, Bisphenols, Per-/Polyfluorinated compounds, Flame Retardants, Cd, Cr, PAHs and Aniline family: MOCA), with the aim to characterise as well as possible the level of exposure to these substances.

Since different priority substances share the same sources or routes of exposure, questions related to exposure to these substances have been included into the basic questionnaire instead of independent questionnaires for each priority substance to avoid an unnecessary duplication of questions and answers. Therefore, we considered more suited and useful to identify specific questions related to priority substances into the interviewer manual, under the column "Justification". This field includes background information for each question, and will allow to identify which specific questions are related to each of the priority substances.

Specific testing of this questionnaire in a subsample of a population still needs to be undertaken. It could be feasible to perform testing with the envisaged group of participants (or a subsample thereof) right before a study using this questionnaire is conducted.

BASIC QUESTIONNAIRE FOR 1st PRIORITY SUBSTANCES

QUESTIONNAIRE INFORMATION	
ID (PARTICIPANT)	_ _ _ _ _ _ _
ID (INTERVIEWER)	_ _ _ _ _ _ _
DATE OF THE INTERVIEW	_ _ _ _ _ _ _ _ _ _ _
START TIME	_ _ _ : _ _ _
END TIME	_ _ _ : _ _ _
PLACE	



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733032.

PERSONAL INFORMATION

Name and surname initials:

Sex: Male Female

SOCIODEMOGRAPHIC INFORMATION

1. What is your birth date? |_|_| month |_|_|_|_| year

2. Where were you, your parents and grandparents born? (include the name of each country)

	In (Country)	In another country	Specify country
Respondent	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
Mother	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
Father	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
Maternal grandmother	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
Maternal grandfather	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
Paternal grandmother	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
Paternal grandfather	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>

3. Which language(s) do you speak at home?

National Language(s) (Country)	Another Language	Specify Language (s)
Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>

4. How long have you been living in...? Please indicate the number of years (or months if less than 1 year) (to be adapted to national characteristics)

This country	Years _ _ Months _ _
This region	Years _ _ Months _ _
This province	Years _ _ Months _ _
This municipality	Years _ _ Months _ _
Current address	Years _ _ Months _ _

5. If you have lived in other households in the past 10 years, complete the following information for each address (starting with the current address and going back to complete the temporal frame)

Address	Street, No.	Municipality	Province/region	Postal Code	Country	Residence period (month and years)	
						Start	Finish
No.1							
No.2							
No.3							
No.4							
No.5							
No.6							

6. What is the highest level of education you attained?

1.No formal education or below primary education (ISCED 0)	<input type="checkbox"/>	6. Short-cycle tertiary education (ISCED 5)	<input type="checkbox"/>
2. Primary education (ISCED 1)	<input type="checkbox"/>	7. Bachelor's or equivalent level (ISCED 6)	<input type="checkbox"/>
3. Lower secondary education,or second stage of basic education (ISCED 2)	<input type="checkbox"/>	8. Master's or equivalent level (ISCED 7)	<input type="checkbox"/>
4. Upper secondary education (ISCED 3)	<input type="checkbox"/>	9. Doctoral or equivalent level (ISCED 8)	<input type="checkbox"/>
5. Post-secondary non-tertiary education (ISCED 4)	<input type="checkbox"/>	10. Don't know	<input type="checkbox"/>

7. What is your current main labour status?

1. Employee working full-time	<input type="checkbox"/>	8. Permanently disabled or/and unfit to work	<input type="checkbox"/>
2. Employee working part-time	<input type="checkbox"/>	9. In compulsory military community or service	<input type="checkbox"/>
3. Self-employed working full-time (including family worker)	<input type="checkbox"/>	10. Fulfilling domestic tasks and care responsibilities	<input type="checkbox"/>
4. Self-employed working part-time (including family worker)	<input type="checkbox"/>	11. Other inactive person	<input type="checkbox"/>
5. Unemployed	<input type="checkbox"/>	12. Other status Specify.....	<input type="checkbox"/>
6. Pupil, student, further training, unpaid work experience	<input type="checkbox"/>	13. Don't know	<input type="checkbox"/>
7. In retirement or in early retirement or has given up business	<input type="checkbox"/>		

8. Which of the following best describes your current professional category?

1. Manager	<input type="checkbox"/>	7. Craft and related trade worker	<input type="checkbox"/>
2. Professional	<input type="checkbox"/>	8. Plant or machine operator or assembler	<input type="checkbox"/>
3. Technician or associate professional	<input type="checkbox"/>	9. Elementary occupation	<input type="checkbox"/>
4. Clerical support worker	<input type="checkbox"/>	10. Armed forces occupation	<input type="checkbox"/>
5. Service or sales worker	<input type="checkbox"/>	11. Other categories Specify.....	<input type="checkbox"/>
6. Skilled agricultural, forestry or fishery worker	<input type="checkbox"/>	12. Don't know	<input type="checkbox"/>

9. Please, give us the following information on all members of your household. (Response options for Education, Labour Status and Professional Category will be the same than in previous questions (6, 7 and 8) and will be given/read by the interviewer)**Answer options:****Education (highest level of education attained)**

1. ISCED 0: no formal education or below ISCED **1. ISCED 1:** primary education **3. ISCED 2:** lower secondary education, or second stage of basic education **4. ISCED 3:** upper secondary education **5. ISCED 4:** post-secondary non-tertiary education **6. ISCED 5:** Short-cycle tertiary education **7. ISCED 6:** Bachelor's or equivalent level **8. ISCED 7:** Master's or equivalent level **9. ISCED 8:** Doctoral or equivalent level **10.** Don't know

Labour status

1. Employee working full-time **2.** Employee working part-time **3.** Self-employed working full-time (including family worker) **4.** Self-employed working part-time (including family worker) **5.** Unemployed **6.** Pupil, student, further training, unpaid work experience **7.** In retirement or in early retirement or has given up business **8.** Permanently disabled or/and unfit to work **9.** In compulsory military community or service **10.** Fulfilling domestic tasks and care responsibilities **11.** Other inactive person **12.** Other status

Professional category

1. Manager **2.** Professional **3.** Technician or associate professional **4.** Clerical support worker **5.** Service or sales worker **6.** Skilled agricultural, forestry or fishery worker work experience **7.** Craft and related trade worker **8.** Plant or machine operator or assembler **9.** Elementary occupation **10.** Armed forces occupation **11.** Other categories

Member	Relationship (partner/ children/another person)	Age	Gender	Education	Labour status	Professional category
No.1						
No.2						
No.3						
No.4						
No.5						
No.6						
No.7						
No.8						

10. Could you provide the approximate range of your total household income? (It is referred to annual gross incomes from all members of your household) (Indicated by each country)

Income category		Income category	
No.1	<input type="checkbox"/>	No.6	<input type="checkbox"/>
No.2	<input type="checkbox"/>	No.7	<input type="checkbox"/>
No.3	<input type="checkbox"/>	No.8	<input type="checkbox"/>
No.4	<input type="checkbox"/>	Don't know	<input type="checkbox"/>
No.5	<input type="checkbox"/>		

RESIDENTIAL ENVIRONMENT AND HOME EXPOSURES

1. In which area is your home located?

1. City centre	<input type="checkbox"/>
2. Near city centre	<input type="checkbox"/>
3. Suburb/metropolitan area	<input type="checkbox"/>
4. Industrial	<input type="checkbox"/>
5. Rural/Village	<input type="checkbox"/>
6. Other areas Specify area.....	<input type="checkbox"/>
7. Don't know	<input type="checkbox"/>

2. Is there any of the following facilities within 300 m of you home?

	Yes	No	Don't know
1. A waste incineration plant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. A site where waste (all waste/ hazardous waste or chemicals?)is dumped	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. A petrol station	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. A metalworking business	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. A scrap yard	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. A site where solvents are used (e.g. painting business)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. A farmland, orchard or vineyard	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. A printing business	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. A dry cleaning service	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. A car repair plant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. A carpentry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. A glass factory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. A steel plant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. A tannery business	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. A construction site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. A recycling plant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. A cement, pesticides or plastic compounds factory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. A place of fertilizer or compost production (including sewage sludge treatment)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. A power plant using coal, oil, wood etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Yes	No	Don't know
20. A metal smeltery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. A site producing or using adhesives	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. A site where computer and/or electronic elements are produced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. A site where photovoltaic devices and solar cells are produced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. A site where epoxy resins are produced or used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. A site where fillers are used or produced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. A site where food and drink containers (plastic and other containers) are produced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. A site where medical equipment is produced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. A site where polycarbonate plastics are produced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. A site where thermal paper is produced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. A site where batteries/candles are produced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. Other industrial facilities Specify facility.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. Which of the following options best describes your home...?

	Yes
1. Detached house	<input type="checkbox"/>
2. Semi-detached house	<input type="checkbox"/>
3. Townhouse	<input type="checkbox"/>
4. A flat/apartment 4.1. Specify floor number.....	<input type="checkbox"/>
5. A farmhouse	<input type="checkbox"/>
6. Other (e.g. caravan, mobile home) 6.1. Specify	<input type="checkbox"/>
7. Don't know <input type="checkbox"/>	

4. Do you know approximately when your home was built?

1. Before 1918	<input type="checkbox"/>	6. 1982-1997	<input type="checkbox"/>
2. 1918-1933	<input type="checkbox"/>	7. 1998-2008	<input type="checkbox"/>
3. 1934-1949	<input type="checkbox"/>	8. After 2008	<input type="checkbox"/>
4. 1950-1965	<input type="checkbox"/>	9. Don't know	<input type="checkbox"/>
5. 1966-1981	<input type="checkbox"/>		

5. What is the living surface (in m²) of your home?m² Don't know

6. Is there a garage directly communicated with your home (attached at the side, or in the basement)? If yes, please specify frequency of use and number of cars parked inside.

	Yes	No	Don't know
Garage communicated with your home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1. Frequency of use (days/week)			<input type="checkbox"/>
2. No. of cars parked			<input type="checkbox"/>

7. What materials are most of the floor covering your home made of?

MATERIALS	Yes
1. Non-textile flooring	
1.1. Wood-parquet	<input type="checkbox"/>
1.2. Wooden planks	<input type="checkbox"/>
1.3. Laminate	<input type="checkbox"/>
1.4. PVC	<input type="checkbox"/>
1.5. Linoleum	<input type="checkbox"/>
1.6. Tiles (e.g. stone, marble, terrazzo)	<input type="checkbox"/>
1.7. Other non-textil material Specify	<input type="checkbox"/>
2. Textile flooring	
2.1. Synthetic fibre	<input type="checkbox"/>
2.2. Natural fibre	<input type="checkbox"/>
2.3. Natural or synthetic fibre with plastic backing	<input type="checkbox"/>
2.4. Other textile material Specify	<input type="checkbox"/>
3. Don't know <input type="checkbox"/>	

8. Please, complete the following information about redecorations and renovations made in your home. Has your home been...?

	Yes	No	Don't know
1. Renovated in the last 2 years? (Major renovations: e.g. new walls, floor, windows...)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Redecorated in the last year? (e.g. painting, varnishing...)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. Do you have or have recently had any of the following problems in your home?

	Yes	No	Don't know
1. Mould or mildew on walls or other home surfaces	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Water damage (e.g. broken pipes, a leaky roof or floods)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Musty or mouldy odour	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Peeling paint on the walls or windowsills	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Black magic dust	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. According to the vehicular traffic, how do you classify the road in which your home is located?

1. Highway	2. Heavy traffic road	3. Frequent traffic road	4. Light traffic road	5. Pedestrian road	6. Don't know
<input type="checkbox"/>					

10.1 At what distance (meters) is your home from a street with constant traffic (e.g. cars continuously circulating)?

|_|_|_|_|m Don't know

11. Does your home have at least one window facing a street with constant traffic?

1. Yes	2. No	3. Don't know
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12. How often do heavy vehicles (buses, trucks...) circulate near your home?

1. Never/Rarely	2. Medium frequency	3. Continuously	4. Don't know
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13. How is your home mainly heated?

1. Individual stove or heater in each room	<input type="checkbox"/>
2. Single-storey heating	<input type="checkbox"/>
3. Central heating	<input type="checkbox"/>
4. District heating	<input type="checkbox"/>
5. Solar heating	<input type="checkbox"/>
6. Open fireplace	<input type="checkbox"/>
7. Other systems Specify.....	<input type="checkbox"/>
8. No heating	<input type="checkbox"/>
9. Don't know <input type="checkbox"/>	

14. Which fuels or sources of energy are used in your home for heating, water heating and cooking? Please, specify how many months each source of energy is used every year.

Source of energy	a. Heating	b. Water heating	5. Cooking
1. Oil	<input type="checkbox"/> No.months.....	<input type="checkbox"/> No.months.....	<input type="checkbox"/> No.months.....
2. Gas	<input type="checkbox"/> No.months.....	<input type="checkbox"/> No.months.....	<input type="checkbox"/> No.months.....
3. Charcoal/Coal	<input type="checkbox"/> No.months.....	<input type="checkbox"/> No.months.....	<input type="checkbox"/> No.months.....
4. Electricity	<input type="checkbox"/> No.months.....	<input type="checkbox"/> No.months.....	<input type="checkbox"/> No.months.....
5. Solar power	<input type="checkbox"/> No.months.....	<input type="checkbox"/> No.months.....	<input type="checkbox"/> No.months.....
6. Wood Pellets	<input type="checkbox"/> No.months.....	<input type="checkbox"/> No.months.....	<input type="checkbox"/> No.months.....
7. Wood Specify.....	<input type="checkbox"/> No.months.....	<input type="checkbox"/> No.months.....	<input type="checkbox"/> No.months.....
8. Other sources Specify.....	<input type="checkbox"/> No.months.....	<input type="checkbox"/> No.months.....	<input type="checkbox"/> No.months.....
9. Don't know	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

15. Is there any smoke extraction system in your home kitchen? If yes, please specify frequency of use

Smoke extraction system	1. Never	2. Occasionaly	3. Sometimes	4. Often	5. Always	6. Don't know
Yes <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No <input type="checkbox"/>						
Don't know <input type="checkbox"/>						

16. How is your house usually ventilated? For each option, please, specify frequency of use (months/year in which mechanical systems are used; hours/day for window ventilation by season)

Ventilation system	
1. Mechanical ventilation system (e.g. fan system)	No <input type="checkbox"/> Yes <input type="checkbox"/> No.months.....Always on.....
2. Window ventilation	Autum-Winter No <input type="checkbox"/> Yes <input type="checkbox"/> No. h/day..... Spring-Summer No <input type="checkbox"/> Yes <input type="checkbox"/> No. h/day.....
3. Don't know <input type="checkbox"/>	

17. How often is general cleaning done in your home?

1. Once a week	2. > Once a week	3. < Once a week	4. Don't know
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

18. Are you in charge of general cleaning of your home?

No Yes, entirely Yes, partially In that case specify the percentage you are in charge of ____%

19. Do you use a vacuum cleaner for general cleaning of your home? If yes, please, specify type and frequency of use

Yes Specify: Vacuum cleaner with air filter Vacuum cleaner with water filter Don't know

1. Once a week	2. > Once a week	3. < Once a week	4. Don't know
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

No

Don't know

20. In the last month, were any of the cleaning products listed below used in your home, at least once a week? If yes, please specify if the cleaning product generally used is a chemical or eco-friendly product

Products	No	Don't know	Yes	If yes, type of product:
1. Cleaning products (e.g. for kitchen, bathroom, floor, windows)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Chemical <input type="checkbox"/> Eco-friendly <input type="checkbox"/> Don't know
2. Floor wax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Chemical <input type="checkbox"/> Eco-friendly <input type="checkbox"/> Don't know
3. Fabric softener	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Chemical <input type="checkbox"/> Eco-friendly <input type="checkbox"/> Don't know
4. Wood varnish	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Chemical <input type="checkbox"/> Eco-friendly <input type="checkbox"/> Don't know
5. Dry cleaning products (e.g. for cleaning upholstery, clothes, carpets)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Chemical <input type="checkbox"/> Eco-friendly <input type="checkbox"/> Don't know
6. Air freshener	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Chemical <input type="checkbox"/> Eco-friendly <input type="checkbox"/> Don't know
7. Solvents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Chemical <input type="checkbox"/> Eco-friendly <input type="checkbox"/> Don't know
8. Spot remover products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Chemical <input type="checkbox"/> Eco-friendly <input type="checkbox"/> Don't know
9. Impregnation fluids (e.g. for upholstery, shoes)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Chemical <input type="checkbox"/> Eco-friendly <input type="checkbox"/> Don't know
10. Other cleaning products Specify.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Chemical <input type="checkbox"/> Eco-friendly <input type="checkbox"/> Don't know

21. Do you have any pets at home? If yes, specify type and number (*If no animal, go to the next section: DIETARY HABITS*)

1. No animal	<input type="checkbox"/>
2. Dog	<input type="checkbox"/> No
3. Cat	<input type="checkbox"/> No
4. Bird	<input type="checkbox"/> No
5. Other animal Specify.....	<input type="checkbox"/> No
6. Other animal Specify.....	<input type="checkbox"/> No

21.1. In the last month, were any of the following products used for your pets?

Product	Yes	No	Don't know
1. Pets grooming products (e.g.shampoos, conditioners, lotions, sprays...)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. External antiparasitic treatments (e.g. lotions, sprays, necklace, collar...)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Other pet products Specify.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Food item	(nearly) never	1-3 per month	1 per week	2-3 per week	4-6 per week	1 per day	2-3 per day	≥4 per day	Don't know
Game meat (pheasant, wild duck, etc.) No. servings	<input type="checkbox"/>								
Tinned meat No. servings	<input type="checkbox"/>								
III. DAIRY PRODUCTS (NOT SKIMMED) AND EGGS									
Butter No. servings	<input type="checkbox"/>								
Milk No. servings	<input type="checkbox"/>								
Cheese No. servings	<input type="checkbox"/>								
Yogurt No. servings	<input type="checkbox"/>								
Eggs No. servings	<input type="checkbox"/>								
IV. CEREALS									
White bread No. servings	<input type="checkbox"/>								
Whole grain bread No. servings	<input type="checkbox"/>								
Cereal products (crackers, rusk...) No. servings	<input type="checkbox"/>								
Barley No. servings	<input type="checkbox"/>								
Oats No. servings	<input type="checkbox"/>								
Bran No. servings	<input type="checkbox"/>								
Other cereals No. servings	<input type="checkbox"/>								
Pasta No. servings	<input type="checkbox"/>								
Rice No. servings	<input type="checkbox"/>								
V. FATS									

4. What materials do you use as cookware for cooking and frying (e.g. pots, pans, fryer, robots, making bread machine etc.)

Use	(nearly) never	1 per month	2-3 per month	1 per week	2-3 per week	4-6 per week	1 per day	Don't know
Steel	<input type="checkbox"/>							
Ceramic	<input type="checkbox"/>							
Glass	<input type="checkbox"/>							
Teflon baking tray/covered pan	<input type="checkbox"/>							
Others <input type="checkbox"/> No <input type="checkbox"/> Yes Specify.....	<input type="checkbox"/>							
Don't know <input type="checkbox"/>								

5. How often have you eaten dishes from communal catering, such as from a canteen, dining hall or cafeteria in the last 4 weeks?

(nearly) never	1 per month	2-3 per month	1 per week	2-3 per week	4-6 per week	1 per day	>1 per day	Don't know
<input type="checkbox"/>								

6. How much water do you drink on average each day? (Do also think of hot beverages and soups!)

Less than 1 l/day	1-2 l/day	2-3 l/day	3-5 l/day	More than 5 l/day	Don't know
<input type="checkbox"/>					

7. What is the main source of your...?

1. drinking water?				2. cooking water?			
Public network	<input type="checkbox"/>	Private well	<input type="checkbox"/>	Public network	<input type="checkbox"/>	Private well	<input type="checkbox"/>
Bottled water (plastic)	<input type="checkbox"/>	Don't know	<input type="checkbox"/>	Bottled water (plastic)	<input type="checkbox"/>	Don't know	<input type="checkbox"/>
Bottled water (glass)	<input type="checkbox"/>	Others	<input type="checkbox"/>	Bottled water (glass)	<input type="checkbox"/>	Others	<input type="checkbox"/>
Specify.....				Specify.....			

8. Do you use water purification devices or water filtering systems for your...

1. drinking water?	2. cooking water?
<input type="checkbox"/> Filter (faucet attachment, refrigerator filter)	<input type="checkbox"/> Filter (faucet attachment, refrigerator filter)
<input type="checkbox"/> Water softener	<input type="checkbox"/> Water softener
<input type="checkbox"/> Other, please specify _____	<input type="checkbox"/> Other, please specify _____
<input type="checkbox"/> No treatment	<input type="checkbox"/> No treatment
<input type="checkbox"/> Don't know	<input type="checkbox"/> Don't know

LIFESTYLE

1. In relation to smoking habits, which of the following options best describes your situation? Please, specify all the information for the situation chosen.

	Yes	No
<p>1.1 I have never smoked (Go to question 2)</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>1.2 I was a smoker but I gave up smoking</p> <p>1.2.1 Age start smoking _ _ <input type="checkbox"/> Don't know</p> <p>1.2.2. Age stop smoking _ _ <input type="checkbox"/> Don't know</p> <p>1.2.3 Type/Variety and average of consumption</p> <p>a. Cigarettes <input type="checkbox"/> No. per day _ _ _ <input type="checkbox"/> Don't know</p> <p>b. Pipes <input type="checkbox"/> No. per day _ _ _ <input type="checkbox"/> Don't know</p> <p>c. Cigars <input type="checkbox"/> No. per day _ _ _ <input type="checkbox"/> Don't know</p> <p>d. Electronic <input type="checkbox"/> No. per day _ _ _ <input type="checkbox"/> Don't know cigarettes</p> <p>e. Products <input type="checkbox"/> No. per day _ _ _ <input type="checkbox"/> Don't know for smoking</p> <p>cessation</p> <p>f. Others <input type="checkbox"/> No. per day _ _ _ <input type="checkbox"/> Don't know</p> <p>Specify.....</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>1.3. I currently smoke (occasionally smoker)</p> <p>1.3.1 Age start smoking _ _ <input type="checkbox"/> Don't know</p> <p>1.3.2 Type/Variety and average of consumption</p> <p>a. Cigarettes <input type="checkbox"/> No. per week _ _ _ <input type="checkbox"/> Don't know</p> <p>b. Pipes <input type="checkbox"/> No. per week _ _ _ <input type="checkbox"/> Don't know</p> <p>c. Cigars <input type="checkbox"/> No. per week _ _ _ <input type="checkbox"/> Don't know</p> <p>d. Electronic <input type="checkbox"/> No. per week _ _ _ <input type="checkbox"/> Don't know cigarettes</p> <p>e. Products <input type="checkbox"/> No. per week _ _ _ <input type="checkbox"/> Don't know for smoking</p> <p>cessation</p> <p>f. Others <input type="checkbox"/> No. per week _ _ _ <input type="checkbox"/> Don't know</p> <p>Specify.....</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>1.4. I currently smoke (daily smoker)</p> <p>1.4.1 Age start smoking _ _ <input type="checkbox"/> Don't know</p> <p>1.4.2 Type/Variety and average of consumption</p> <p>a. Cigarettes <input type="checkbox"/> No. per day _ _ _ <input type="checkbox"/> Don't know</p> <p>b. Pipes <input type="checkbox"/> No. per day _ _ _ <input type="checkbox"/> Don't know</p> <p>c. Cigars <input type="checkbox"/> No. per day _ _ _ <input type="checkbox"/> Don't know</p> <p>d. Electronic <input type="checkbox"/> No. per day _ _ _ <input type="checkbox"/> Don't know cigarettes</p> <p>e. Products <input type="checkbox"/> No. per day _ _ _ <input type="checkbox"/> Don't know for smoking</p> <p>cessation</p> <p>f. Others <input type="checkbox"/> No. per day _ _ _ <input type="checkbox"/> Don't know</p> <p>Specify.....</p>	<input type="checkbox"/>	<input type="checkbox"/>

2. How many people living in this house smoke regularly (indoors)? For each of them, please indicate the average number of cigarettes smoked indoors per day

Member	Smoking habit
No.1	No. cigarettes/day __ __ __ <input type="checkbox"/> Don't know
No.2	No. cigarettes/day __ __ __ <input type="checkbox"/> Don't know
No.3	No. cigarettes/day __ __ __ <input type="checkbox"/> Don't know
No.4	No. cigarettes/day __ __ __ <input type="checkbox"/> Don't know

3. Do those who visit this house smoke indoor?

Never	Rarely (<1/month)	Sometimes (<1/week)	Once a week	2-3 times/week	4-6 times/week	Don't know
<input type="checkbox"/>						

4. How long, on a daily average, do you usually spend in the following indoor places where people smoke?

	Never	<1h/day	1-4h/day	>4h/day	Don't know
a. At workplace	<input type="checkbox"/>				
b. At transports (car, train, bus...)	<input type="checkbox"/>				
c. At restaurants, pubs, clubs, events	<input type="checkbox"/>				
d. At friends', relatives' or neighbours' homes	<input type="checkbox"/>				
e. Other indoor places	<input type="checkbox"/>				

5. From the following list of alcoholic drinks, please, indicate your frequency of consumption during the previous 12 months?

	Never	<1/month	1-3/month	1/week	2-3/week	4-6/week	>6/week	Don't know
1. Beer (a glass, 200 cc)	<input type="checkbox"/>							
2. Wine, champagne, cider (a glass, 125 cc)	<input type="checkbox"/>							
3. Spirits <40% alcohol (fruit liquors. A glass, 50 cc)	<input type="checkbox"/>							
4. Spirits >40% alcohol (whisky, gin, vodka... A glass, 50 cc)	<input type="checkbox"/>							
5. Alcoholic cocktails (a glass, 50 cc)	<input type="checkbox"/>							

6. Which of the following best describes your current physical exercise? Please do not take into account your physical activity at work

1. Never do physical activity	<input type="checkbox"/>
2. Light physical exercise for relaxation fewer than three times a week	<input type="checkbox"/>
3. Medium and intensive physical exercise fewer than three times a week	<input type="checkbox"/>
4. Intensive physical exercise at least three times a week for 10 minutes or more	<input type="checkbox"/>
5. Daily exercise over 30 minutes a day	<input type="checkbox"/>
6. Don't know	<input type="checkbox"/>

7. How much time on average do you spend in the following places (referred to workdays and weekends)?

	Workdays	Weekends
1. Inside your home	_ _ hours _ _ minutes <input type="checkbox"/> Don't know	_ _ hours _ _ minutes <input type="checkbox"/> Don't know
2. Inside other houses	_ _ hours _ _ minutes <input type="checkbox"/> Don't know	_ _ hours _ _ minutes <input type="checkbox"/> Don't know
3. In other indoor spaces (e.g. at workplace, shopping centre, sports club, cinema, restaurant...)	_ _ hours _ _ minutes <input type="checkbox"/> Don't know	_ _ hours _ _ minutes <input type="checkbox"/> Don't know
4. In your car	_ _ hours _ _ minutes <input type="checkbox"/> Don't know	_ _ hours _ _ minutes <input type="checkbox"/> Don't know
5. In other closed vehicles for daily commuting (e.g. bus, car, train...)	_ _ hours _ _ minutes <input type="checkbox"/> Don't know	_ _ hours _ _ minutes <input type="checkbox"/> Don't know
6. Outdoor traffic (on foot, bicycle, motorbike, skating, at train stations or bus stops...)	_ _ hours _ _ minutes <input type="checkbox"/> Don't know	_ _ hours _ _ minutes <input type="checkbox"/> Don't know
7. Outdoors, away from home (park, garden, forest, beach, outdoor sports area...)	_ _ hours _ _ minutes <input type="checkbox"/> Don't know	_ _ hours _ _ minutes <input type="checkbox"/> Don't know

Nail polish remover	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Traditional cosmetics (kohl, surma, kajal, tiro, etc.) (TO BE ADAPTED IF IT IS NEEDED)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other products Specify.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BODYCARE	Never	Ocasionally	Several times a month	Once a week	Everyday	Don't know
Perfume / eau de Cologne	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Body soap	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Body or hand lotion (cream, milk...)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sun cream (sunscreen)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sun tan lotion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anti-aging cream	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Deodorant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Shaving cream or aftershave lotion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Body oil	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Skin bleaching products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other products Specify.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9.1. How often (times per day) do you wash your hands? No. times/day |_|_|_| Don't know

10. Did you carry out any of the following activities as DIY activities or hobbies and/or were you exposed to any of these substances in these activities in the last month? (Please, do not count your professional activity)

	Yes	No	Don't know
SURFACE TREATMENT			
Apply varnish, finish or seals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mix or apply paints or lacquers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Strip or thin paint	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Apply fillers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of anti-corrosive agents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other products, specify.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Yes	No	Don't know
CLEANING AND REPARATION PRODUCTS			
Use solvents or degreasers (for cleaning sticky/greasy things)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Application of glues or adhesives	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Application of lubricating oils	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Degrease tools, machines or electronics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use cleaning chemicals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of computer and/or electronic products repairing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other products, specify.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HOME REPAIRS/MAINTENANCE AND CONSTRUCTION ACTIVITIES			
Wood processing or use of wood preservatives	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Glass processing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of Portland cement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of surface protection agents (spray) for clothes, windows or other applications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of assembly foam	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other products, specify.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
GARDENING			
Use of compost or sewage sludge (as fertilizer)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of phosphate fertilizers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other products, specify.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HANDLING METALS			
Welding	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use lead, mercury or other metals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of ferrous metal alloys, stainless steel or other alloys processing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of non-ferrous processing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other products, specify.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DYES AND INKS			
Use dyes (for hair or textiles)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of inks (e.g. tattoo, specially yellow, orange and red colors)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of inks (e.g. tattoo, specially green and light-blue)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of inks (e.g. tattoo, specially black tattoos)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Printing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other products, specify.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Yes	No	Don't know
PLASTIC HANDLING			
Use of plastic gloves	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of polycarbonate plastics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of plastic products processing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of reusable food and drink containers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other products, specify.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
OTHER PRODUCTS AND ACTIVITIES			
Use of kiln for pottery and ceramics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of fireplace or exposure to combustion products (in/outdoors)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Auto body repairing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sports that require the use of safety equipment (i.e. helmets, protective eye visors)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of ski wax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Apply epoxy resins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Leather processing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Traditional (analog) photography (including photographic films)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of photovoltaic devices and solar cells	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
OTHER PRODUCTS AND ACTIVITIES NOT ABOVE-MENTIONED			
Other products/activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Specify activity.....			
Specify substances exposed to			
Other products/activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Specify activity.....			
Specify substances exposed to			

11. Please, indicate how much time per day, on average, you have used electronic devices such as mobile phones, computers, tablets, GPS... in the last month?

1. Workdays	2. Weekends
<p>1.1. Portable devices _ _ hours _ _ minutes <input type="checkbox"/> Don't know</p> <p>1.2. Desk devices _ _ hours _ _ minutes <input type="checkbox"/> Don't know</p>	<p>2.1. Portable devices _ _ hours _ _ minutes <input type="checkbox"/> Don't know</p> <p>2.2. Desk devices _ _ hours _ _ minutes <input type="checkbox"/> Don't know</p>

12. Do you regularly wear plastic or rubber shoes such as e.g. flip-flops, beach shoes, swimming shoes, Crocs ® or clogs without socks?

Yes No Don't know

13. Do you have a habit of putting objects made of plastic (e.g. pens, glasses or toys) in your mouth and chewing on them?

Yes No Don't know

If yes, please specify the frequency:

Daily	Several times per week	Less often	Don't know
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

OCCUPATION

CURRENT OCCUPATIONAL EXPOSURE

1. Please, indicate the sector of industry/workplace where you work in (refer to annex IV, interviewer manual)

.....
 If other, please specify:

2. Please, describe your current job:

3. How long have you been doing this job? Specify years or months, if less than one year

|_|_| years |_|_| months

4. Do you come into contact with the following substances on your job?

4.1. Oil, gasoline, or diesel	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify: (e.g. oil refining/ petrochemical plants/ petroleum refinery, garage work, contaminated soil renovation, other job, which?)
4.2. Creosote, creosote oil, coal tar	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify: (e.g. creosote work, wood impregnation, pillar work, rail work, contaminated soil renovation, other job, which?)
4.3. Bitumen, bitumen products	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify: (e.g. road paving, bitumen work, bitumen roofing, waterproofing, contaminated soil renovation, other job, which?)
4.4. Combustion products, including gasoline/diesel exhausts, ash or soot	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify: (e.g. aluminium production, chimney sweeping, coking plants, firefighting/ fire practice/ fire prevention training, foundry industry, garage work, heating/ thermal power plants, metallurgic industry, mining, vehicle inspection, vehicle depots, waste incineration)
4.5. Polycyclic aromatic hydrocarbons (PAHs), if not included in other substance group/categories	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.6. Metallic dust	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.7. Mercury	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.8. Cadmium	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.9. Chromium	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:

			
4.10. Other metals	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.11. Pharmaceuticals	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.12. Paints/ coatings	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.13. Printing inks	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:(e.g. ink production, printing industry, other job, which?)
4.14. Dyes, azo dyes and pigments (tattoo inks, sulphur dyes, indigo compounds)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify: (job/working task, what kind of dye?)
4.15. Diisocyanates,4,4'-Methylenediphenyl diisocyanate (MDI)-based lacquers, foams and adhesives, toluene diisocyanate (TDI) and MDI or TDI-based polyurethane polymers	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.16. Varnishes	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.17. Solvents	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.18. Plasticisers	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.19. Pesticides, biocides or disinfection products (herbicides, fungicides, insecticides or bactericides)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.20. Cosmetics or hair treatment products (hair dyes etc.)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.21. Anilines (e.g. aniline, 4,4'-methylenedianiline (=4,4'-MDA), 4,4'-methylenebis[2-chloroaniline] (= MOCA), o- and p-toluidine, p-phenylenediamine (= p-PDA), 1,3-diphenylguanidine), if not included in other substance/ group	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.22. Rubber chemicals	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.23. Flame retardants	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.24. Nanomaterials	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.25. Photoresist/antireflective coatings	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:

4.26. Other hazardous materials, hazardous waste or other chemicals (e.g. contaminated soil renovation)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
4.27. Other compounds Specify.....	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:

5. Please, indicate the main work tasks/activities that you perform regularly:

Task/activity 1

- Duration of the tasks (hours in a work shift):
.....
- Frequency of the tasks (days/week or days/month, please circle):
.....
- Chemicals/substances produced, used or handled (please, refer to category list of question 4):
.....
- Use of PPE (please, specify the type):
.....
- Availability of collective protective measures (please, specify the type):
.....

Task/activity 2

- Duration of the tasks (hours in a work shift):
.....
- Frequency of the tasks (days/week or days/month, please circle):
.....
- Chemicals/substances produced, used or handled (please, refer to category list of question 4):
.....
- Use of PPE (please, specify the type):
.....
- Availability of collective protective measures (please, specify the type):
.....

Task/activity 3

- Duration of the tasks (hours in a work shift):
.....
- Frequency of the tasks (days/week or days/month, please circle):
.....
- Chemicals/substances produced, used or handled (please, refer to category list of question 4):
.....
- Use of PPE (please, specify the type):
.....
- Availability of collective protective measures (please, specify the type):
.....

6. Do you use Personal Protective Equipment (PPE)?

Yes No Don't know

If yes, please specify:
.....

7. In the working environment in which you perform working tasks/activities are there technical risk management measures (e.g. local exhaust ventilation, compartmentalisation of the exposure source...) available?

Yes No Don't know

If yes, please specify:

8. Are you subjected to a health surveillance program at work?

Yes No Don't know

If yes: Does the health surveillance program to which you are subjected include biological monitoring (measurement of chemicals or their metabolites in e.g. blood or urine samples)?

Yes No Don't know

If yes, please specify:

- What chemicals/substances have been monitored (if known, please specify the CAS number)?
-

- How often is the biological monitoring carried out?
-
-

9. Are your family/household members working with chemicals in their job?

Yes No Don't know

If yes, specify

OCCUPATIONAL HISTORY

1. Please, fill the following questions for each of the previous jobs where you have worked in the past 25 years:

Previous job	Sector of industry/ workplace *	Job description	Job duration
Job no.1			__ years __ months
Job no.2			__ years __ months
Job no.3			__ years __ months

* refer to annex IV, interviewer manual. If other, please specify.

2. Did you come into contact with the following substances on your previous job?

2.1. Oil, gasoline, or diesel	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify: (e.g. oil refining/ petrochemical plants/ petroleum refinery, garage work, contaminated soil renovation, other job, which?)
2.2. Creosote, creosote oil, coal tar	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify: (e.g. creosote work, wood impregnation, pillar work, rail work, contaminated soil renovation, other job, which?)
2.3. Bitumen, bitumen products	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify: (e.g. road paving, bitumen work, bitumen roofing, waterproofing, contaminated soil renovation, other job, which?)
2.4. Combustion products, including gasoline/diesel exhausts, ash or soot	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify: (e.g. aluminium production, chimney sweeping, coking plants, firefighting/ fire practice/ fire prevention training, foundry industry, garage work, heating/ thermal power plants, metallurgic industry, mining, vehicle inspection, vehicle depots, waste incineration)
2.5. Polycyclic aromatic hydrocarbons (PAHs), if not included in other substance group/categories	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.6. Metallic dust	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.7. Mercury	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.8. Cadmium	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.9. Chromium	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.10. Other metals	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:

			
2.11. Pharmaceuticals	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.12. Paints/ coatings	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.13. Printing inks	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:(e.g. ink production, printing industry, other job, which?)
2.14. Dyes, azo dyes and pigments (tattoo inks, sulphur dyes, indigo compounds)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify: (job/working task, what kind of dye?)
2.15. Diisocyanates,4,4'-Methylenediphenyl diisocyanate (MDI)-based lacquers, foams and adhesives, toluene diisocyanate (TDI) and MDI or TDI-based polyurethane polymers	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.16. Varnishes	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.17. Solvents	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.18. Plasticisers	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.19. Pesticides, biocides or disinfection products (herbicides, fungicides, insecticides or bactericides)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.20. Cosmetics or hair treatment products (hair dyes etc.)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.21. Anilines (e.g. aniline, 4,4'-methylenedianiline (=4,4'-MDA), 4,4'-methylenebis[2-chloroaniline] (= MOCA), o- and p-toluidine, p-phenylenediamine (= p-PDA), 1,3-diphenylguanidine), if not included in other substance/ group	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.22. Rubber chemicals	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.23. Flame retardants	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.24. Nanomaterials	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.25. Photoresist/antireflective coatings	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:
2.26. Other hazardous materials, hazardous waste or	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:

other chemicals (e.g. contaminated soil renovation)				
2.27. Other compounds Specify.....	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>	Specify:

3. Were you subjected to a health surveillance program at work in the past?

Yes No Don't know

If yes: Did this health surveillance program to which you were subjected include biological monitoring (measurement of chemicals or their metabolites in e.g. blood or urine samples)?

Yes No Don't know

If yes, please specify:

- What chemicals/substances have been monitored (if known, please specify the CAS number)?

-
- How often is the biological monitoring carried out?
-

HEALTH

1. Anthropometric measurements	Don't know
1.1 How tall are you without shoes (in cm)? _____ cm	<input type="checkbox"/>
1.2. How much do you weight without clothes and shoes (in kg)? _____ kg	<input type="checkbox"/>

2. Weight change	Yes	No	Don't know
2.1 Has your weight changed in the past year?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2. Have you lost weight in the past year? Specify how much your weight has changed (in kg) _____ kg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.3. Have you gained weight in the past year? Specify how much your weight has changed (in kg) _____ kg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. Do you have or have you ever had any of the following diseases or conditions, diagnosed by a medical doctor? If yes, please specify how old you were when this was first diagnosed		
3.1 Asthma (allergic asthma included)	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.2 Chronic bronchitis, chronic obstructive pulmonary disease (COPD), emphysema	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.3 Myocardial infarction	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.4 Coronary heart disease (angina pectoris)	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.5 High blood pressure (hypertension)	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____

**3. Do you have or have you ever had any of the following diseases or conditions, diagnosed by a medical doctor?
If yes, please specify how old you were when this was first diagnosed**

3.6 Elevated blood cholesterol	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis — —
3.7 Stroke (cerebral haemorrhage, cerebral thrombosis)	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis — —
3.8 Rheumatoid arthritis (inflammation of the joints)	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis — —
3.9 Osteoarthritis (arthrosis, joint degeneration)	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis — —
3.10 Osteoporosis	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis — —
3.11 Low back disorder or other chronic back defect	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis — —
3.12 Neck disorder or other chronic neck defect	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis — —
3.13 Diabetes	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis — —
3.14 Thyroid condition	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis — —
3.15 Allergy, such as rhinitis, eye inflammation, dermatitis, food allergy or other (allergic asthma excluded)	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis — —

**3. Do you have or have you ever had any of the following diseases or conditions, diagnosed by a medical doctor?
If yes, please specify how old you were when this was first diagnosed**

3.16 Stomach ulcer (gastric or duodenal ulcer)	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.17 Cirrhosis of the liver, liver dysfunction	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.18 Kidney disease or dysfunction	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.19 Cancer (malignant tumour, also including leukaemia and lymphoma) (see next question to specify kind of cancer)	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.20 Severe headache such as migraine	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.21 Urinary incontinence, problems in controlling the bladder or other gallbladder problems	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.22 Chronic anxiety	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.23 Chronic depression	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.24 Other mental health problems	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.25 Spinal cord disorders	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____

**3. Do you have or have you ever had any of the following diseases or conditions, diagnosed by a medical doctor?
If yes, please specify how old you were when this was first diagnosed**

3.26 Attention deficit disorders (ADD, ADHD)	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.27 Autism	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.28 Asperger syndrome	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.29 Down syndrome	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.30 Parkinson's disease	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.31 Learning disability	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.32 Other neurological disorders	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
3.33 Permanent injury or defect caused by an accident	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
(For women only) Gynaecological diseases	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____
(For men only) Prostate diseases	Never <input type="checkbox"/> Yes, in the past 12 months <input type="checkbox"/> Yes, more than 1 year ago <input type="checkbox"/> Don't know <input type="checkbox"/>	Age at diagnosis ____

**3. Do you have or have you ever had any of the following diseases or conditions, diagnosed by a medical doctor?
If yes, please specify how old you were when this was first diagnosed**

Other diseases or conditions. Specify:	Never <input type="checkbox"/>	Age at diagnosis _____
	Yes, in the past 12 months <input type="checkbox"/>	
	Yes, more than 1 year ago <input type="checkbox"/>	
	Don't know <input type="checkbox"/>	

4. If you answered "Yes" for cancer, please specify what kind of cancer.

Bladder <input type="checkbox"/>	Brain <input type="checkbox"/>	Lymphoma/ Hodgkin's disease <input type="checkbox"/>	Rectum (rectal) <input type="checkbox"/>	Thyroid <input type="checkbox"/>
Blood <input type="checkbox"/>	Gallbladder <input type="checkbox"/>	Melanoma <input type="checkbox"/>	Skin (non- melanoma) <input type="checkbox"/>	Uterus (uterine) <input type="checkbox"/>
Bone <input type="checkbox"/>	Kidney <input type="checkbox"/>	Mouth/ tongue/lip <input type="checkbox"/>	Skin (don't know what kind) <input type="checkbox"/>	Other <input type="checkbox"/> Specify.....
Breast <input type="checkbox"/>	Larynx/ Windpipe <input type="checkbox"/>	Nervous System <input type="checkbox"/>	Rectum (rectal) <input type="checkbox"/>	Don't know <input type="checkbox"/>
Cervix (cervical) <input type="checkbox"/>	Leukaemia <input type="checkbox"/>	Ovary (ovarian) <input type="checkbox"/>	Soft tissue (muscle or fat) <input type="checkbox"/>	
Colon <input type="checkbox"/>	Liver <input type="checkbox"/>	Pancreas (pancreatic) <input type="checkbox"/>	Stomach <input type="checkbox"/>	
Esophagus (esophageal) <input type="checkbox"/>	Lung <input type="checkbox"/>	Prostate <input type="checkbox"/>	Testis (testicular) <input type="checkbox"/>	

5. During the past two weeks, have you used any medicines that were prescribed for you by a doctor for...?

High blood pressure Yes No Don't know
Lowering blood cholesterol level Yes No Don't know
Diabetes Yes No Don't know

5.1. Which medicines prescribed for you by a doctor you have used in the past two weeks, excluding those before mentioned? Please, indicate the commercial name of the medicine, the indication, as well as the strength of the drug, dose and frequency of use.

Commercial name	Indication	Dose	Frequency of use	Starting date	Ending date

6. Have you been vaccinated for?

Seasonal flu	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
Hepatitis B	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
Polio	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>

MMR (measles, mumps, rubella)	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
DTP (diphtheria, tetanus, pertussis)	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
Varicella (chicken pox)	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>

Please, answer questions 7 to 13 on your reproductive history **(ONLY FOR WOMEN)**

7. Are you pregnant at present?	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>
8. Have you ever been pregnant? (Including current pregnancy, live births, miscarriages, stillbirths, tubal pregnancies or abortions). If yes, specify number. If not, go to question 11.	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/> No. ____ ____

9. Please, complete the following information for each of your pregnancies				
	Abortion	Live birth	Polyembryotic	Birth defects
Pregnancy No.1	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>			
Pregnancy No.2	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>			
Pregnancy No.3	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>			
Pregnancy No.4	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>			
Pregnancy No.5	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>			
Pregnancy No.6	Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/>			

10. Are you breast feeding or have breastfed? If so, please indicate the length of breastfeeding. For women with several children, specify total months of breastfeeding.

Yes, I am breastfeeding **Specify length:** ____ weeks (if less than 1 month) ____ months Don't know

Yes, I had breast-fed **Specify length:** ____ weeks (if less than 1 month) ____ months Don't know

Yes, both **Specify length:** ____ weeks (if less than 1 month) ____ months Don't know

No

11. Have there been time periods when you have attempted to have a child but have not succeeded or it took over 12 months to succeed?

I don't know, because we or I have never tried to have a baby

No

Yes Most recently ____ years ago

12. Have you ever been examined or been treated for infertility? Yes No Don't know

12.1 What was the reason for your infertility?

Damage of the Fallopian tube (e.g. obstructions)

Disturbance of the ovulation

Endometriosis

Reasons related to man
(e.g. weak sperm movement or slow sperm count)

Reason is unclear

Other reason

Specify _____

13. Which of the following options best describes your menstrual cycle?

I have menstrual periods If yes, specify length (on average)____ __ days Don't know

My period stopped permanently menopause

If so, specify type of menopause:

Natural

Hormone therapy

Surgical

Don't know

Please, answer questions 14 and 15 on your reproductive history (ONLY FOR MEN)

14. Have there been time periods when you have attempted to have a child but have not succeeded or it took over 12 months to succeed?

I don't know, because we or I have never tried to have a baby

No

Yes Most recently ____ __ years ago

15. Have you ever been examined or been treated for infertility? Yes No Don't know **15.1 What was the reason for your infertility?**

Wake sperm movement

Slow sperm count

Abnormal sperm shape

Reasons related to woman
(e.g. damage of the Fallopian tube,
disturbance of the ovulation, endometriosis)

Reason is unclear

Other reason

Specify _____

16. Do you have or ever had amalgam fillings or dental sealant in your teeth?

Yes, amalgam fillings

Yes, dental sealant

Yes, both

No

Don't know

16.1 In how many teeth? ___ ___ amalgam fillings Don't know ___ ___ dental sealant Don't know

16.2 When was the amalgam filling placed last time? (specify days/months/years ago)

___ ___ days ___ ___ months ___ ___ years Don't know

16.3 When was the dental sealant placed last time? (specify days/months/years ago)

___ ___ days ___ ___ months ___ ___ years Don't know

16.3 When was the amalgam filling removed from your teeth last time? (specify days/months/years ago)

___ ___ days ___ ___ months ___ ___ years Don't know

16.2 When was the dental sealant removed from your teeth last time? (specify days/months/years ago)

___ ___ days ___ ___ months ___ ___ years Don't know

17. Have you done any body modifications (excluding medical interventions)? If yes, specify how long since you got the first body modification

Piercings No Yes ___ ___ days ___ ___ months ___ ___ years

Tattoos No Yes ___ ___ days ___ ___ months ___ ___ years

If yes, please specify the colour group(s) used in this tattoo:

Black	Yellow, orange and/or red	Green and/or light blue	Others	Don't know
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Implants No Yes ___ ___ days ___ ___ months ___ ___ years

Other modifications No Yes ___ ___ days ___ ___ months ___ ___ years

Specify.....

18. Do you have any artificial joints, pins, plates, metal suture material, or other types of metal objects in your body? (Do not include piercings, crowns, dental braces or retainers, shrapnel, or bullets.)

Yes No Don't know

19. How often do you usually wear metallic jewellery (e.g. rings, earrings, necklaces)

1. Never/Rarely	2. Sometimes (few times a month)	3. Always (almost daily)	4. Don't know
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

20. Do you use glasses and/or contact eye lenses?

Yes, glasses

Yes, contact lenses

Yes, both

No

Don't know



HBM4EU

science and policy
for a healthy future

HORIZON2020 Programme
Contract No. 733032 HBM4EU

Annex 2.1.2

Interviewer Manual to the basic questionnaire for 1st priority substances

WP 7

Task 7.3

D 7.3

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Co-authors

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1. Interviewer manual of basic questionnaire

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2. Interviewer manual of specific questions on 1st priority substances

1st priority substances	Name (Partner)
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This document has been created for the HBM4EU project. HBM4EU project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733032.

2 Aims

The present manual contains instructions intended to facilitate the field work. This manual is designed specifically for interviewers in order to be considered as a reference tool at the time of collecting information. The success of the surveys depends largely on it.

Likewise, the manual provides a justification of the objective of each question included in the basic questionnaire. The basic questionnaire has been designed to collect all the necessary information concerning individual characteristics of the participants and on different sources and routes of exposure to 1st-priority substances selected for study (Phthalates/DINCH, Bisphenols, Per-/Polyfluorinated compounds, Flame Retardants, Cd, Cr, PAHs and Aniline family: MOCA), with the aim to characterise as well as possible the level of exposure to all these substances.

3 Considerations about basic questionnaire

This questionnaire aims to collect information in a standardized way from each participant, as this will enable to obtain comparable results across countries involved in the HBM4EU study. It has been designed to collect all the necessary information concerning individual characteristics on the following topics: I) sociodemographic characteristics; II) residential environment and home exposures; III) dietary habits; IV) lifestyle; V) occupational exposures; VI) health data.

4 Information for interviewers

To ensure that this questionnaire is administered in a standardized way, please follow the considerations listed below:

- This questionnaire only must be applied to the person selected to participate in HBM4EU study.
- Questions and responses must be literally read by the interviewers, always following the fixed order. To dispel misunderstanding among participants, please do speak clear and loud enough and at a normal rate to be adequately heard by the interviewee.
- The response given by the interviewee must be accepted by the interviewer. In those cases, where a certain response is not feasible or convincing the interviewer should formulate the question again to receive a new answer. If not, the given response will be finally accepted by the interviewer.
- All the questions of this questionnaire must be answered by the interviewee. In case the interviewee does not provide a precise response after a reasonable period of time, or refuse to answer, the question will be considered as "Don't know".

5 Basic questionnaire interviewer manual

I. SOCIO-DEMOGRAPHIC SECTION

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
<p>1. What is your birth date?</p>	<p>This question is essential to identify potential differences in human exposures, as well as susceptibility associated with the age. Potential determinant of exposure to phthalates, BPA, PFASs, FR, Cd, Cr, PAHs and anilines (1st priority substances).</p>	<p>Month and year of birth will be asked here.</p>
<p>2. Where were you, your parents and grandparents born?</p>	<p>It is necessary to collect information on participants' country of origin, as it could lead to different exposure levels to priority substances (due to genetic characteristics, lifestyle or dietary habits, among others).</p>	<p>In this question, information on countries where the participants and their direct family members (parents and grandparents) were born will be asked for.</p>
<p>3. Which language(s) do you speak at home</p>	<p>Asking for languages spoken at home we can collect additional information on the origin of the participant and also on cultural factors.</p>	<p>Please, indicate the national language (or languages, for countries with several official languages) spoken at home. If other language(s) different from national languages is (are) spoken at home, specify which one(s).</p>
<p>4. How long have you been living in...? Please indicate the number of years (or months if less than 1 year)</p>	<p>This question is intended to gather information on internal and external migrations, since it could be associated with changes in chemical exposure levels.</p>	<p>According to geographical characteristics of each country, please ask for the length of time living in this country/region/province/municipality/current address. Select "Don't know" if the interviewee does not remember that time.</p>
<p>5. If you have lived in other households in the past 10 years, complete the following information for each address (starting with the current address and going back to complete the temporal frame)</p>	<p>This question provides information on residential history, which helps to identify the potential influence of the place of residence on the results of the study.</p>	<p>Please, provide complete information on this question. If address is not remembered, indicate at least the municipality or postal code. Regarding the period of time living in each place, try to collect information on how many months and years, if possible.</p>

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
6. What is the highest level of education you attained?	The level of education is a proxy of the socio-economic situation, which could be used to develop an indicator of occupational social class. Determinant of exposure to phthalates, BPA, PFASs, FR, Cd ,Cr, PAHs (1st priority substances).	Please, indicate the level completed by the interviewee. When required, check the right category in Annex 2.1.2.1 "International Standard Classification of Education"
7. What is your current main labour status?	The labour status is also a proxy of the socio-economic situation, which could be used to develop an indicator of occupational social class. Determinant of exposure to phthalates, BPA, PFASs, FR, Cd, Cr, PAHs and anilines (1st priority substances).	Please note that this question is referred to the labour which the interviewee dedicates most of her/his time to.
8. Which of the following best describes your current professional category?	The professional category is also a proxy of the socio-economic situation, which could be used to develop an indicator of occupational social class. Determinant of exposure to phthalates, PFASs, BPA, FR, Cd, Cr, PAHs and anilines (1st priority substances).	Please note that this question is referred to the current professional category in which the interviewee spends most of her/his time in. Check the ISCO 08 manual (Annex 2.1.2.2) to answer this question.
9. Please, give us the following information on all members of your household	The number of people living in the same household, as well as their education, labour status and professional category, is an indicator of the socio economic situation of the household.	Please, complete the table with the information given for every household member (including members currently living at home, or outside but economically dependent from the household, e.g. students).
10. Could you provide the approximate range of your household 's total gross income?	The income level is an indicator of the socio economic status of the household. Determinant of exposure to phthalates, PFASs, BPA, FR, Cd, Cr and PAHs (1st priority substances).	This question is referred to total annual gross incomes from all members of the household.

II. RESIDENTIAL ENVIRONMENT AND HOME EXPOSURES

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
<p>1. In which area is your home located?</p>	<p>This question aims to characterize the environment where the participant lives, as differences could exist in human exposure associated with the area of residence. Residential area impacts exposure to fine particles, PAHs and other air pollutants, and it could be also a determinant of exposure to phthalates, BPA, FR, Cd and Cr (1st priority substances).</p>	<p>This question has to be answered according to the area in which the home is located. Please, only one from the given options must be selected (best fit).</p>
<p>2. Is there any of the following facilities within 300 m of you home?</p>	<p>It is necessary to collect information on facilities considered as potential sources of exposure to pollutants, which might lead to differences in human exposure levels. Likewise, this question provides information on the general characteristics of the living environment (e.g. heavily industrialized area...) Large scale combustion facilities nearby households increase the PAH exposure and other air pollutants. Determinant of exposure to phthalates, BPA, Cd and Cr (1st priority substances).</p>	<p>Please, ask only for those facilities located near the participant's home (300 m). Multiple answers are possible. If the concept of distance is not well understood by the interviewee, some explanation can be given as: "facilities within 15 minutes walking distance from your home". When appropriate (e.g. facilities not included in the given options or not sure of the right category), specify the name of other facilities located near household.</p>
<p>3. Which of the following options best describes your home...?</p>	<p>Asking for home types allows gathering additional information on the characteristics of the dwelling and the environment where the participant live. Moreover, the home type could contribute to different exposure to contaminants (e.g. floor level, isolation...)</p>	<p>Indicate the option that best fits from the given options. When necessary, specify other home types. Please note that semi-detached house is a single-family home that is built to share one common wall with the adjacent home, having both of them the same design. On the other hand, townhouses are traditionally row houses with two or more floors, where homes are connected, on both sides and on all levels.</p>

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
4. Do you know approximately when was your home built?	Home's age is a direct indicator of the indoor environment and also of the materials and compounds used for building. Since some compounds have been banned and others have emerged, this question will provide information on the potential contribution of home's age on environmental exposures levels.	Please select the year range where the year of building is more likely included, according to the participant's answer. If the interviewee has not a clear idea or a reference of the age of building, then select Don't Know.
5. What is the living surface (in m²) of your house?	The home surface, together with the number of household members, provides information on the socio-economic status of the participant. Furthermore, this surface might also affect the indoor concentration of certain compounds, which leads to differences in levels of exposure.	This question refers to indoor living spaces (terraces, gardens... should not be included). Participants can provide an estimation or rounding answers if they do not know exactly the home surface.
6. Is there a garage directly communicated (attached to the side, in the basement) with this home? If yes, please specify frequency of use and cars parked in it.	Direct air connection between garage and living spaces may clearly result in PAH exposure and other combustion products.	Please note that this question aims to collect information on communicated garages in houses (e.g. attached to walls, in the basement) and also in flats or apartments (in the basement of the building). Specify also the number of days/week in which the garage is used and the number of cars generally parked.

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
<p>7. What materials are most of the floor covering your home made of?</p>	<p>The floor covering is considered as an important source of indoor exposure to certain compounds, especially phthalates, BPA, PFASs and FR. Furthermore, floor covering favouring dust accumulation could be a way for humans to be exposed to other pollutants at home. Phthalates and flame retardants are used as plasticizers(softeners) in floor covering. They are volatile and can be found in house dust, too. One of the newer phthalates, DPHP, is used in both carpet coating and also inside cars. The more space in the flat has PVC floor covering, the bigger is the surface for possible phthalates exposure.</p> <p>Regarding flame retardants, despite some compounds have been forbidden (e.g. PBDEs), exposure to other organohalogen and organophosphorus compounds could occur at home due to the previous presence of these materials in floor covering.</p>	<p>This question aims to collect information on the main type of materials used to cover more than 50% of the floor. When appropriate (e.g. floor covering not included in the given options or not sure about the right category), specify the name of other floor coverings given by the interviewee. If a clear response is not obtained, then select Don't Know.</p> <p>Synthetic or natural fiber with plastic backing refers to fiber that is fixed on a flat, sometimes bendable surface made out of a rubber or plastic. This surface is often not seen easily as it is the layer applied to the ground (the backside or backing), with the fiber side facing upwards.</p>
<p>8. Please, complete the following information about redecorations and renovations made in your home. Has your home been...</p> <p>8.1. Renovated in the last 2 years?</p> <p>8.2. Redecorated in the last year?</p>	<p>Renovations and redecorations at home entail the use of a wide of variety of compounds, such as paints, varnish, metals, and plastics, among others. This could contribute to chemical exposure in people living in houses where recent renovations and redecorations were conducted. Especially renovation can include the exchange of floor or wall covering. The procedure of removing the former covering with a new one with a potentially higher concentration of phthalates, BPA or flame retardant could increase exposure to these compounds.</p>	<p>Please, consider only renovations conducted in the last 2 years, and redecorations in the last year.</p> <p>Renovations refer to major changes made at home for a better state, such as removing floor or windows, rebuilding walls or roof, remodelling kitchen or bathroom...</p> <p>Redecorations refer to changes in decorative scheme or appearance, such as applying paint, varnish, changing wallpapers, among others.</p>

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
9. Do you have any of the following problems in your home?	Mould or mildew on walls and water damage, among others, are frequent domestic problems which can provide information on the quality of the living environment, as well as on participant's socio-economic status.	Complete the table with the information on domestic problems given by the interviewee.
10. According to the vehicular traffic, how do you classify the road in which your home is located?	Traffic density has a direct impact on exposure to fine particles, PAHs, and other air pollutants, as well as Cd and Cr (1st priority substances).	Please, indicate the type of road according to vehicular traffic. This classification includes categories which vary from highest frequency of traffic (highway) to lowest one (pedestrian road).
10.1 At what distance (meters) is your home from a street with constant traffic?	Distance to heavy traffic has a direct impact on exposure to fine particles and PAHs, and other air pollutants, as well as Cd and Cr (1st priority substances).	Please note that constant traffic means cars continuously circulating.
11. Does your home have at least one window facing a street with constant traffic?	This window may be open at times increasing exposure to air pollutants, which could a source of the exposure to PAHs, Cd an Cr (1st priority substances).	Please note that constant traffic means cars continuously circulating.
12. How often do heavy vehicles (buses, trucks...) circulate near your home?	Heavy traffic intensity has a direct impact on exposure to fine particle, PAHs, and other air pollutants, as well as Cd and Cr (1st priority substances).	This question only refers to heavy vehicles, such as buses and trucks. Please, select the option that best fits to interviewee situation.
13. How is your home mainly heated?	Heating system has an important contribution on the indoor levels of certain compounds, specially the number and types of stoves/fireplaces enhance exposure to fine particle, PAH, hazard combustion products, and heavy metals among others. Hence, it is necessary to identify the main heating system at home to explore its association with human exposure levels to these compounds.	This question is intended to identify the main heating system used at homes, that is, the system used to heat more than 50% of the home surface, regardless of other systems used at home. District heating refers to urban heating (which comes from outside the house). When none heating system at all is available at home, then select "No heating". In case of selecting heating system not included in the given options or not sure of the right category, it is necessary to specify the name of these other heating system. If the interviewee has not a clear response, then select Don't Know.

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
14. Which fuels or energy sources are mainly used in your home for heating, water heating and cooking? Please, specify how many months each source of energy is used every year	This question includes information on fuels and other sources of energy used for heating, water heating and cooking. Should the energy sources release smoke indoors, this is relevant for exposure to fine particles, PAHs and other combustion products.	Please, specify which options are used for heating, water heating and cooking at home, and when proceeding, indicate the number of months in which they are used.
15. Is there any smoke extraction system in your home kitchen? If yes, please specify frequency of use	Smoke extraction systems in kitchens help to reduce indoor concentration of certain chemicals, such as combustion products. Hence, it is important to collect information on these smoking extraction systems, as well as on their frequency of use to better characterize home exposure to contaminants.	Smoke extraction system refers to those systems located in the kitchen (especially near of the cooking area, e.g. extractor hood), aimed to evacuate and remove fumes, smoke and combustion products. Please, indicate the frequency of use of this system when appropriate.
16. How is your house usually ventilated? For each option, please, specify frequency of ventilation (months/year in which mechanical systems are used; hours/day for window ventilation by season)	Ventilation at home (mechanical or manual) is related with the exchange of circulating compounds, affecting to indoor concentrations of these compounds at home, and consequently to human exposure levels. This is relevant for fine particle and PAH exposure especially if there is heavy traffic outside the point of fresh air entrance.	Please, ask for ways of the ventilation of home, and their frequency of use. Please note that mechanical ventilation usually entails the presence of electromechanical systems (e.g. fans) to drive air flow inside and outside home. In case this mechanical system is automatically working, then indicate Always working in the questionnaire.
17. How often is general cleaning done in your home?	House cleaning is associated with the concentration of substances, including chemical pollutants inside home, such as flame retardants and phthalates, among others. This variable might affect human exposure indoors, since house cleaning involves the mobilization and elimination of dust-borne chemicals deposited in floor, windows, etc.	Please note that general cleaning refers to a wide cleaning in the whole dwelling involving floors, dust, regardless of the person involved on this task.
18. Are you in charge of general cleaning of your home?	As mentioned above, house cleaning might affect human exposure to substances accumulated indoors, especially by those in charge of the general cleaning, due to their direct contact.	Please, specify the contribution of the interviewee to the general cleaning of the house (if he/she has a partial contribution, ask for an estimation of the percentage of the workload usually done).

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
<p>19. Do you use a vacuum cleaner for general cleaning of your home? If yes, please, specify type of vacuum cleaner and use frequency</p>	<p>The use of vacuum cleaner for house cleaning involves the mobilization of substances accumulated in domestic dust. This might affect the concentrations of circulating compounds inside home (e.g. flame retardants and phthalates), and therefore, the exposure of residents to these compounds.</p>	<p>Please, indicate if a vacuum cleaner is used for house cleaning. When appropriate, specify the frequency of use, as well as the type of filter. Note that water filters refer to those vacuum cleaners having a container for water, while air filters do not need water for working but a bag or a tank where the dust is accumulated.</p>
<p>20. In the last month, were any of following cleaning products used in your home, at least once a week? If yes, please specify if the cleaning product generally used is a chemical or eco-friendly product</p>	<p>Certain household cleaning products contain chemical substances which residents could be exposed to (e.g. PFASs in furniture polish/ specific cleaning agents/ impregnation/ coating agents/ paints). Hence, a proper characterization of the exposure via questionnaire to these products is needed to identify their potential contribution on human exposure.</p>	<p>This question aims to identify those products used at home at least once a week in the last month, irrespective of the person in charge of their application. For those products used, please specify if it is a chemical or eco-friendly product. Eco-friendly products refer to those products without chemical substances in their composition (or reduced concentrations). They can be identified by the labelled and specifications in their packaging. Please, select "don't know" if the interviewee is unable to differentiate chemical from eco-friendly products. If applicable (e.g. a product not included in the given options or not sure of the right category), specify the name of product given by the interviewee. If the interviewee does not have a clear response about the use of a product, then select Don't Know.</p>
<p>21. Do you have any pets at home? If so, specify type and number</p>	<p>Pets are considered as a source of home exposure to certain compounds (allergens, pesticides, parabens, among others), because of the deposition or accumulation of these substances in the hair. Likewise, this question could be also helpful for studying the relationship between having pets at home and the development of allergic or atopic diseases, such as asthma, eczema...</p>	<p>Note down if certain animals are present at home, and their number. Please, specify other animals not included but reported by the interviewee. If there are no pets at home, jump to the next section "Dietary habits".</p>

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
21.1. In the last month, were any of the following products used for your pets?	Pets products could be a source of exposure to certain substances, such as insecticides, parabens, among others. Information on this matter has to be collected for a proper characterization of human exposure to these compounds.	Please, collect complete information on pet's product used in the last month. Overall, grooming products refer to cosmetic products for pets (e.g. shampoos, lotions...) while external antiparasitic treatments are used to control parasitic pest (fleas, ticks...). IF applicable (e.g. a product not included in the given options or not sure of the right category), specify the name of the product given by the interviewee. If the interviewed has not a clear response about the use of a product, then select Don't Know.

III. DIETARY HABITS

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
<p>1. How often did you consume the following food items in the last 4 weeks?</p>	<p>This question is necessary to assess the overall dietary habits of participants. Certain foodstuffs can be the source of exposure to prioritized substances. Smoked food, grilled over an open flame/burning embers, fried food. All of these ways of food processing can generate PAHs. Phthalate exposure has been shown to be positively correlated with consumption of: cereal products, fats, fatty dairy products (e.g. butter, cheese), offal, and various sweets (e.g. ice cream, hazelnut spread, and jelly candies) as well as ready meals, fruits and vegetables, fish, meat (poultry) and eggs. Can food/drinks could be a determinant of the exposure to BPA. Fish, seafood and microwave popcorn are sources of exposure to PFASs. Seafood consumption is also a determinant of the exposure to Cd and Cr. Regarding flame retardants, the following food items have been found to be associated with the exposure to this group of substances: eggs and egg products, milk and dairy products, meat and meat products, animal and vegetable fats and oils, fish and other seafood.</p>	<p>Please note that the period of interest is 4 weeks in order to assess the typical diet. Think about all the food you eat, both meals and snacks, either at home or outside, please specify all amount of foods you consumed including also ingredients of any meal (e.g. salad for sandwiches, cheese for pasta or sandwiches...) Please, show Annex 2.1.2.3 "Food serving sizes gallery" to the interviewee to check the serving sizes of each food consumed in the last 4 weeks. Indicate the frequency of consumption of each food, as well as the number of servings, according to the pictures included in the gallery.</p>
<p>2. Do you consume dietary supplements (e.g. vitamins and minerals)? If so, please indicate frequency, starting date and finishing date (if the use has finished).</p>	<p>Human metabolism of some xenobiotics could be affected/modulated by the concentration of vitamins.</p>	<p>Information on vitamins and supplements (not for medicines), has to be collected here. When appropriate (e.g. a product not included in the listed options or not sure of the right category), specify the name of the product given by the interviewee. If the interviewee has not a clear response about the use of a product, then select Don't know.</p>

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
3. In the last 4 weeks, did you consume fast food /take away food (including beverages)? If so, how was it packed and how often did you consume it?	This question evaluates exposure to food contact materials possibly containing phthalates, BPA, PFASs and other priority substances.	Please note that participants can select multiple type of food contact materials, most of them considered as possible sources of prioritized substances. However, other food contact materials such as aluminum or glass are possible.
4. What materials do you use as cookware for cooking and frying (e.g. pots, pans, fryer, robots, making bread machine etc.)	This question evaluates the possible exposure to prioritized substances (e.g. BPA, PFASs) from cross contamination from other food products.	Please note that participants can select multiple type of materials, most of them considered as possible sources of prioritized substances, other ones such as aluminum or glass are possible.
5. How often have you eaten at restaurant or communal catering (canteen, dining hall or cafeteria) in the last 4 weeks?	This question evaluates the exposure to material possibly containing phthalates, BPA, PFASs and other priority substances.	Please note that multiple answers are possible and the type of selected material referred only to other possible sources of prioritized substances, such as aluminum or glass are possible.
6. How much water do you drink on average each day? (Consider also hot beverages and soups!)	This question evaluates the amount of water consumed daily by the interviewees.	Please note that the period of interest is 4 weeks in order to assess the current amount of water consumption. Also consider any other beverages you drink at home and outside home, including hot beverages, tea, coffee and soup.
7. What is the main source of your drinking water?And cooking water?	This question is essential to understand what kind of water is consumed most frequently by study participants because the different sources of water have their own bromatological and chemical composition. Together with the home address it provides valuable exposure information. Often, liquids are within bottles with a cap or a layer made out of plastic that is in contact with the liquid. This is why bottled water can potentially be a source of phthalate and BPA exposure. Origin could be also associated with the exposure to PFASs.	This question refers to water consumed at home or elsewhere (e.g., tap water, bottled water). Consider also water use to prepare hot beverages (tea, coffee), and for preparing meals. Please, only indicate the main source of drinking and cooking water.
8. Do you use water purification devices or water filtering systems for your drinking water? And cooking water?	This question evaluates the kind of filters used by the participants at home because filters modify and purify water and consequently they can influence the levels of chemicals of interest.	This refers to any water treatments done at home, do not include treatments performed by the municipality.

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
<p>9. Do you drink beverages different from water (fruit juices, ice tea, soft drinks...)? If yes, specify which of the following bottling types do you usually consume</p>	<p>This question assesses the possible exposure to prioritized substances from food contact materials through food (cross contamination). Often, liquid containers have a cap or an internal layer made out of plastic that is in contact with the liquid they contain. This is why bottled water can potentially be a source of phthalate and BPA exposure.</p>	<p>Please note that and type of selected material referred only to possible sources of prioritized substances. Other sources such as aluminum or glass are also possible.</p>
<p>10. Do you use containers for fridge storage of food or for long-time storage elsewhere? If so, how often do you use it?</p>	<p>This question evaluates the possible exposure to prioritized substances (e.g. PFASs, BPA) from food contact materials.</p>	<p>Please note that information on the use of each type of containers has to be collected. Containers used for general food storage (cold and non-cold storage) are included here.</p>
<p>11. Do you use containers for preparing or heating food in the microwave oven? If so, how often?</p>	<p>This question evaluates the possible exposure to prioritized substances (e.g. PFASs, BPA) from food contact materials (cross contamination).</p>	<p>Please note that multiple answers are possible and type of selected material referred only to possible sources of prioritized substances. Other sources such as aluminum or glass are possible.</p>
<p>12. Do you use bread toaster?</p>	<p>Heavily toasted bread certainly contains PAHs although any type of toast contains to some extent those substances.</p>	<p>Please note that the period of interest is 4 weeks in order to assess the frequency of using toaster (at home and elsewhere).</p>

IV. LIFESTYLE

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
<p>1. In relation to smoking habits, which of the following options best describes your situation? Please, specify all the information for the situation chosen.</p>		<p>Please, indicate the situation of the participant in relation to smoking habits. Specify the type of product and the frequency of smoking (occasionally, daily and ex-smokers). If the participant has never smoked, 'no' can be ticked under point 1.1 and skip the remaining parts of the question.</p>
<p>2. How many people living in this house smoke regularly (indoors)? For each of them, please indicate the average number of cigarettes smoked indoors per day</p>	<p>Information on smoking habits and passive exposure to tobacco smoke has to be collected since these are well known sources of exposure to a wide variety of substances such as PAHs, Cd, Cr, BPA and anilines. The concentration of nicotine metabolites has been shown to be significantly associated with the concentration of phthalates.</p>	<p>Please, complete this table for all of the household members that smoke inside the home.</p>
<p>3. Do people who visit this house smoke indoor?</p>		<p>Here, ask for the frequency in which people visiting the house smoke (indoors)</p>
<p>4. How long, on a daily average, do you usually spend in the following indoor places where people smoke?</p>		<p>Here it is important to ask only for these indoor places where people smoke, not for general indoor places.</p>
<p>5. From the following list of alcoholic beverages please, indicate your frequency of consumption during the previous 12 months?</p>		<p>Alcohol has been identified as an important confounder in many epidemiological studies. Hence, information on alcohol consumption in the last year has to be collected.</p>
<p>6. Which of the following options best describes your current physical exercise? Please do not take into account your physical activity at work</p>	<p>This question aims to collect information on general physical exercise. Physical exercise might affect some factors related to metabolism of xenobiotics in humans, as has been observed in epidemiological studies, which could lead to differences in exposure levels to these compounds.</p>	<p>This question includes information on overall physical exercise, excluding working activity. Please, note that intensive exercise refers to any sweating activity that also makes breathing harder.</p>

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
<p>7. How much time do you spend on average in the following places (referred to workdays and weekends)?</p>	<p>The time spent on a daily basis in different environments will provide essential information on potential sources of exposure to contaminants in humans, as well as on their contribution on total exposure burden.</p> <p>Newer cars' interiors can be a source for phthalate exposure (e.g. DPHP), BPA or FR. The newer the car, the more likely a higher exposure. The more time spent in a new car, the more likely is higher exposure.</p>	<p>Please, compile information on time spent in each of the given environments, during workdays and weekends. Time should refer to an average of time based on the daily habits of the interviewee. 'In your car' refers to the total time spent seated in the car with the doors closed, no matter if the engine is turned on or not.</p>
<p>8. How old is the car you spend most time in?</p>	<p>Car's age is directly related to the materials used for its construction. Newer cars' interiors can be a source for phthalate (e.g. DPHP) and flame retardant exposure. The newer the car, the more likely a higher exposure.</p>	<p>Please, indicate the approximated age of the car most often used by the interviewed (e.g. more than 50 % of the total car commuting). The total age of the car is referred to as the timespan between when the car was first bought and now.</p>
<p>9. How often did you use the following cosmetic and hygiene products in the last month? For each product, please indicate the commercial brand you mostly use.</p>	<p>Personal care products and cosmetics are widely used.</p> <p>Complete information on the use of these products is needed to a proper characterization of the exposure in humans. Phthalate exposure has been shown to be positively correlated with the use of deodorant, body lotion, anti-ageing cream and perfume as well as make-up and cosmetic products in general. BPA exposure could be also associated with the use of these products.</p> <p>Specific types, such as water resistant make up, nail polish... could be associated with the exposure to PFASs.</p>	<p>Complete information on personal care products and cosmetic used by the interviewee in the last month has to be collected. For each listed product, please indicate yes/no, and the commercial brand for those used by the interviewees. If the interviewee cannot give an answer for a product, please invite him/her to check whether the mentioned product is available at home at the time of the interview. The best would be to show a list of the cosmetic products in question and let the participant to read it along with the interviewer. This would make it easier and quicker to point out the cosmetic items used.</p>
<p>9.1. How often (times per day) do you wash your hands?</p>	<p>Frequency of hand washing is a determinant of the exposure to different compounds (e.g. phthalates)</p>	<p>Please indicate here the times per day.</p>

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
<p>10. Did you carry out any of the following activities as DIY activities or hobbies and/or were you exposed to any of these substances in such activities in the last month?? (Please, do not consider your professional activity)</p>	<p>Some hobbies and DIY activities involve the use of certain products which could affect exposure to first priority substances. This question will help to explore the relationship between the products used in the last month and the exposure levels to the studied analytes.</p>	<p>Please note that this question refers to exposures occurred in the last month. For each group of products, indicate if they have been used by the interviewee. When applicable (e.g. a product not included in the given options or not sure about the right category), then select other products and specify the name of the product given by the interviewee. If the interviewee has not a clear response about the use of a product, then select Don't Know. For those questions covering the use of inks (e.g. tattoos), please note that they refer to people using these substances (e.g. tattoos artists) but not to people receiving a tattoo (this aspect is covered in Health Section, question no. 17)</p>
<p>11. Please, indicate how much time on a daily average, you use electronic devices such as mobile phones, computers, tablets, GPS... in the last month?</p>	<p>This question aims to collect information on use of electronic devices, since BPA and FR are frequently used in their manufacture.</p>	<p>Please, indicate the overall time average dedicated to handle electronic devices, including portable and desk devices, in the last month.</p>
<p>12. Do you wear regularly plastic or rubber shoes such as e.g. flip-flops, beach shoes, swimming shoes, Crocs® or clogs without socks?</p>	<p>Rubber shoes often contain phthalates. Direct contact with (sweating) skin can therefore be a source of phthalate exposure.</p>	<p>Please, ask for the regular use of the type of plastic or rubber shoes mentioned. The use is limited to cases wearing shoes without socks. Regular use means more than 3 times per week.</p>
<p>13. Do you have a habit of putting objects made of plastic (e.g. pens, glasses or toys) in your mouth and chewing on them? If yes, please specify the frequency</p>	<p>Determinant of exposure to phthalates, among other substances.</p>	<p>Ask here if the interviewee has habit of chewing on plastic objects.</p>

V. OCCUPATION

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
<p>1. Please, indicate the sector of industry/workplace in which you are currently working (refer to annex 2.1.2.4): If other, please specify:</p>	<p>The sector of industry is needed to classify the field of work.</p>	<p>Annex 2.1.2.4: The Statistical classification of economic activities in the European Community, abbreviated as NACE (NACE Rev. 2). Annex 2.1.2.4 can be found attached to D7.3 at the end of this document (main classes).</p>
<p>2. Please, describe your current job:</p>	<p>Job description gives information about the type of work where possible exposures could occur.</p>	<p>Detailed description of work tasks is important to correctly interpret the participants' exposure conditions.</p>
<p>3. How long have you been doing this job? Specify years (or months if less than one year)</p>	<p>Length of time working is important when assessing effects of occupational exposures</p>	<p>Total working time in this job in years and months is asked.</p>
<p>4. Which of the following substances are you exposed to in your job?</p>	<p>This question is essential to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.</p>	<p>It is important to let participants enough time to think about the possible exposure to these substances. Category of chemicals is listed in questions 4.1 - 4.27 considering various exposure conditions. Some of the 1st priority substances under HBM4EU are mentioned separately in a specified exposure category.</p>
<p>4.1. Oil, gasoline, or diesel</p>	<p>The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.</p>	<p>Oil products represent a general source of exposure to polycyclic aromatic hydrocarbons (PAHs), which are 1st priority substances under HBM4EU. Please, select from the list or otherwise specify the work where you come into contact with these substances (e.g., oil refining/ petrochemical plants/ petroleum refinery, garage work, contaminated soil renovation)</p>
<p>4.2. Creosote, creosote oil, coal tar</p>	<p>The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.</p>	<p>There is a risk of PAH exposure in contact with creosote and tar. Please, select from the list or otherwise specify the work where you come into contact with these substances (e.g. creosote work, wood impregnation, pillar work, rail work, contaminated soil renovation)</p>

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
4.3. Bitumen, bitumen products	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Bitumen products are a source of exposure to PAHs. Please, select from the list or otherwise specify the work where you come into contact with these substances (e.g. road paving, bitumen work, bitumen roofing, waterproofing, contaminated soil renovation)
4.4. Combustion products, including gasoline/diesel exhausts, ash or soot	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as and to avoid possible bias.	Combustion products including fine particles have an impact on PAH exposure. Please, select from the list or otherwise specify the work where you come into contact with combustion products (e.g. aluminum production, chimney sweeping, coking plants, firefighting/ fire practice/ fire prevention training, foundry industry, garage work, heating/thermal power plants, metallurgic industry, mining, vehicle inspection, vehicle depots, waste incineration)
4.5. Polycyclic aromatic hydrocarbons (PAHs), if not included in other substance group/categories	PAHs are 1 st priority substances under HBM4EU.	Other possible sources of PAH exposure. In case some specific PAHs are used, identification of PAH compounds (name, CAS-number, etc.) is informative in order to correctly interpret the results of the questionnaire.
4.6. Metallic dust	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Please, specify the work task where you come into contact with metallic dust. Identification of metals/substances in dust (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire. Metallic dust could be a source of exposure to hazardous (heavy) metals including 1 st priority substances under HBM4EU cadmium and chromium (VI).
4.7. Mercury	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and of biological monitoring as well as to avoid possible bias.	Please, specify the work task where you come into contact with mercury or mercury compounds. In the case of mercury compounds, specify compounds (name, CAS-number, etc.).

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
4.8. Cadmium	Cadmium is one of the 1 st priority substances under HBM4EU.	Please, specify the work where you come into contact with cadmium or cadmium compounds. In case of cadmium compounds, specify individual compounds (name, CAS-number, etc.).
4.9. Chromium (VI)	Chromium (VI) is one of the 1 st priority substances under HBM4EU.	Please, specify the work where you come into contact with chromium or chromium compounds. In the case of chromium compounds, specify compounds (name, CAS-number, etc.).
4.10. Other metals	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Identification of metals and metal compounds (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire.
4.11. Pharmaceuticals	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of the effective drug and its ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire e.g. the analgesic acetaminophen (paracetamol) is a major metabolite of aniline, which is one of the 1 st priority substances under HBM4EU.
4.12. Paints/ coatings	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and of biological monitoring as well as to avoid possible bias.	Specification of the paint and its ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire.
4.13. Printing inks	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and of biological monitoring as well as to avoid possible bias.	Specification of the ink and its ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire. Printing inks could contain e.g. anilines and PAHs, which are 1 st priority substances under HBM4EU. Please, specify the work where you come into contact with printing inks (e.g. ink production, printing industry, other job, which?).

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
4.14. Dyes, azo dyes and pigments (tattoo inks, sulphur dyes, indigo compounds)	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of the dye or pigment and their ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire. Dyes could contain e.g. anilines, which are 1 st priority substances under HBM4EU.
4.15. Diisocyanates,4,4'-Methylenediphenyl diisocyanate (MDI)-based lacquers, foams and adhesives, toluene diisocyanate (TDI) and MDI or TDI-based polyurethane polymers	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of each of the diisocyanates (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire. Some anilines (e.g.methylenedianiline (MDA) and toluenediamine (TDA)) are metabolites of diisocyanates. Please, specify the work where you come into contact with diisocyanates.
4.16. Varnishes	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of varnishes and their ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire.
4.17. Solvents	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of solvents and their ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire.
4.18. Plasticisers	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of the plasticisers (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire. Plasticisers could contain e.g. phthalates, which are 1 st priority substances under HBM4EU.
4.19. Pesticides, biocides or disinfection products (herbicides, fungicides, insecticides or bactericides)	The question aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of each of the pesticides and their ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire. Pesticides could contain e.g. various anilines, which are 1 st prioritysubstances under HBM4EU.

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
4.20. Cosmetics or hair treatment products (hair dyes, etc.)	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of cosmetics or hair treatment products/hair dyes and their ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire. Cosmetics and hair treatment products could contain e.g. various anilines, which are 1 st priority substances under HBM4EU.
4.21. Anilines (e.g. aniline, 4,4'-methylenedianiline (=4,4'-MDA), 4,4'-methylenebis[2-chloroaniline] (= MOCA), o- and p-toluidine, p-phenylenediamine (= p-PDA), 1,3-diphenylguanidine), if not included in other substance/ group	Anilines are 1 st priority substances under HBM4EU.	Other possible sources of exposure to anilines (especially aniline, 4,4'-MDA, MOCA, o- and p-toluidine, p-PDA, 1,3-diphenylguanidine). In case some specific anilines are used, identification of each of the aniline (name, CAS-number, etc.) is informative in order to correctly interpret the results of the questionnaire.
4.22. Rubber chemicals	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Identification of specific rubber chemicals (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire. Rubber chemicals could contain e.g. various anilines and PAHs, which are 1 st priority substances under HBM4EU. Please, specify the work where you come into contact with rubber chemicals.
4.23. Flame retardants	Flame retardants are 1 st priority substances under HBM4EU.	Identification of each of the flame retardants and their ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire.
4.24. Nanomaterials	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of nanomaterials and nanoparticles (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire.

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
4.25. Photoresist/antireflective coatings	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of each of the photoresist/antireflective coatings and their ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire.
4.26. Other hazardous materials, hazardous waste or other chemicals (e.g. contaminated soil renovation)	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of other hazardous materials, hazardous waste or other chemicals (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire. These could include e.g. various mixtures, which are 1 st priority substances under HBM4EU.
4.27. Other compounds	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of each other compound used (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire.

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
<p>5. Please, indicate the main work tasks/activities that you perform regularly: Task/activity 1, 2 and 3:</p> <p>* Duration of the tasks (hours in a work shift):</p> <p>* Frequency of the tasks (days/week or days/month):</p> <p>* Chemicals/substances produced, used or handled (please, refer to category list of question 4):</p> <p>* Use of Personal Protective Equipment (PPE) (please, specify the type):</p> <p>* Availability of collective protective measures (please, specify the type):</p>	<p>The main work tasks/activities give insight into participants' regular exposure conditions.</p> <p>Duration provides information about the total length of possible exposure in that task per workday.</p> <p>Frequency provides information about frequency of possible exposure in that task on a workweek or month basis.</p> <p>This question provides information about possible sources of exposure in main work tasks/activities. This question provides information on the PPE used in that task, which is an important exposure modifier.</p> <p>This question provides information on collective protective measures in that task, which are also important exposure modifiers.</p>	<p>There are three main work tasks in the questionnaire and the following five questions are asked in each of them.</p> <p>This is the average time devoted to that task every workday (less than one hour could be expressed as minutes).</p> <p>Frequency is expressed as days per week or days per month. Please, fulfill how many days and circle or write down the selection, week or month. Referred to the category list of question 4. If there is answered "yes" or "specify" -selection is fulfilled.</p> <p>Please, specify the type of PPE (e.g. respirator and type, hand protection/gloves, protective clothing, eye protection).</p> <p>Please, specify the type of collective protective measures used (e.g. general ventilation, local ventilation, compartmentalization).</p> <p>Please, collect the above information from each of the tasks developed by the interviewee (1, 2, 3 or more, according to the individual case).</p>
<p>6. Do you use Personal Protective Equipment (PPE)?</p>	<p>This question provides information on PPE used in general.</p>	<p>Please, specify the type of PPE (e.g. respirator and type, hand protection/gloves, protective clothing, eye protection).</p>

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
<p>7. In the working environment in which you perform working tasks/activities are there technical risk management measures (e.g. local exhaust ventilation, compartmentalisation of the exposure source...) available?</p>	<p>This question provides information on collective protective measures in the workplace in general.</p>	<p>Please, specify the type of measures used (e.g. general ventilation, local ventilation, compartmentalization)</p>
<p>8. Are you subjected to a health surveillance program at work? If yes: Does the health surveillance program to which you are subjected include biological monitoring (measurement of chemicals or their metabolites in e.g. blood or urine samples)?</p>	<p>This question provides information whether biological monitoring is carried out.</p>	<p>If answer is yes: -What chemicals/substances have been monitored (if known, please specify the CAS number)? Specification of the biological matrix used for the analysis (e.g. chromium in urine) is also essential. -How often is the biological monitoring carried out?</p>
<p>Other information on occupational exposure: 9.. Are your family/household members working with chemicals in their job?</p>	<p>This question provides additional information on possible exposures.</p>	<p>If yes, specify: -How many members are working with chemicals? -Which chemicals are involved?</p>
Occupational history		
<p>1. Please, fill the following questions for each of your previous jobs in the past 25 years.</p>	<p>The industry sector is needed to classify the field of work. Job description gives information about the type of work where possible exposures can occur. The working period is important when assessing effects of exposure.</p>	<p>Annex 2.1.2.4: The Statistical classification of economic activities in the European Community, abbreviated as NACE (NACE Rev. 2). Annex 2.1.2.4 at the end of this document (main classes and sub- classification). Detailed description of work tasks is important to correctly interpret the participants' exposure conditions. The total working time in this job (in years and months) is asked.</p>

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
2. Did you come into contact with the following substances on your job?	This question is essential to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	It is important to let participants enough time to think about the possible exposure to these substances. A category list follows in questions 4.1 - 4.27 considering various exposure conditions. Some of the 1 st priority substances under HBM4EU are mentioned separately in specified exposure category.
2.1. Oil, gasoline, or diesel	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Oil products are a general source of exposure to polycyclic aromatic hydrocarbons (PAHs), which are 1 st priority substances under HBM4EU. Please, select from the list or otherwise specify the work where you come into contact with these substances (e.g. oil refining/ petrochemical plants/ petroleum refinery, garage work, contaminated soil renovation)
2.2. Creosote, creosote oil, coal tar	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	There is a risk of PAH exposure in contact with creosote and tar. Please, select from the list or otherwise specify the work where you come into contact with these substances (e.g. creosote work, wood impregnation, pillar work, rail work, contaminated soil renovation)
2.3. Bitumen, bitumen products	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Bitumen products are a source of exposure to PAHs. Please, select from the list or otherwise specify the work where you come into contact with these substances (e.g. road paving, bitumen work, bitumen roofing, waterproofing, contaminated soil renovation)

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
2.4. Combustion products, including gasoline/diesel exhausts, ash or soot	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Combustion products including fine particles have an impact on PAH exposure. Please, select from the list or otherwise specify the work where you come into contact with combustion products (e.g. aluminum production, chimney sweeping, coking plants, firefighting/ fire practice/ fire prevention training, foundry industry, garage work, heating/ thermal power plants, metallurgic industry, mining, vehicle inspection, vehicle depots, waste incineration)
2.5. Polycyclic aromatic hydrocarbons (PAHs),if not included in other substance group/categories	PAHs are 1 st priority substances under HBM4EU.	Other possible sources of PAH exposure. In the case of some specific PAHs are used,specification of PAH compounds (name, CAS-number, etc.) is informative in order to correctly interpret the results of the questionnaire.
2.6. Metallic dust	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias. Metallic dust could be a source of hazardous (heavy) metals including 1 st priority substances under HBM4EUcadmium and chromium (VI).	Please, specify the work task where you come into contact with metallic dust. Specification of metals/substances in dust (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire.
2.7. Mercury	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Please, specify the work task where you come into contact with mercury or mercury compounds. In the case of mercury compounds, specify compounds (name, CAS-number, etc.).
2.8. Cadmium	Cadmium is one of the1 st priority substances underHBM4EU.	Please, specify the work where you come into contact with cadmium or cadmium compounds. In the case of cadmium compounds, specify compounds (name, CAS-number, etc.).

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
2.9. Chromium (VI)	Chromium (VI) is one of the 1 st priority substances under HBM4EU.	Please, specify the work where you come into contact with chromium or chromium compounds. In the case of chromium compounds, specify compounds (name, CAS-number, etc.).
2.10. Other metals	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of metals and metal compounds (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire.
2.11. Pharmaceuticals	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of the effective drug and its ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire, e.g. analgesic paracetamol is a major metabolite of aniline, which is one of the 1 st priority substances under HBM4EU.
2.12. Paints/ coatings	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of the paint and its ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire.
2.13. Printing inks	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of the ink and its ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire. Printing inks could contain e.g. anilines and PAHs, which are 1 st priority substances under HBM4EU. Please, specify the work where you come into contact with printing inks (e.g. Ink production, printing industry, other job, which?).
2.14. Dyes, azo dyes and pigments (tattoo inks, sulphur dyes, indigo compounds)	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of the dye or pigment and their ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire. Dyes could contain e.g. anilines, which are 1 st priority substances under HBM4EU.

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
2.15. Diisocyanates,4,4'-Methylenediphenyl diisocyanate (MDI)-based lacquers, foams and adhesives, toluene diisocyanate (TDI) and MDI or TDI-based polyurethane polymers	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of the diisocyanate (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire. Some anilines (e.g.methylenedianiline (MDA) and toluenediamine (TDA)) are metabolites of diisocyanates. Please, specify the work where you come into contact with diisocyanates.
2.16. Varnishes	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of varnishes and their ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire.
2.17. Solvents	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of solvents and their ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire.
2.18. Plasticisers	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of compounds (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire. Plasticisers could contain e.g., phthalates, which are 1 st priority substances under HBM4EU.
2.19. Pesticides, biocides or disinfection products (herbicides, fungicides, insecticides or bactericides)	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of pesticides and their ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire. Pesticides could contain e.g. various anilines, which are 1 st priority substances under HBM4EU.
2.20. Cosmetics or hair treatment products (hair dyes etc.)	The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.	Specification of cosmetics or hair treatment products/hair dyes and their ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire. Cosmetics and hair treatment products could contain e.g. various anilines, which are 1 st priority substances under HBM4EU.

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
<p>2.21. Anilines (e.g. aniline, 4,4'-methylenedianiline (=4,4'-MDA), 4,4'-methylenebis[2-chloroaniline] (= MOCA), o- and p-toluidine, p-phenylenediamine (= p-PDA), 1,3-diphenylguanidine), if not included in other substance/group</p>	<p>Anilines are 1stpriority substances under HBM4EU.</p>	<p>Other possible sources of exposure to anilines (especially aniline, 4,4'-MDA, MOCA, o- and p-toluidine, p-PDA, 1,3-diphenylguanidine). In case of some specific anilines are used, the identification of each aniline compound (name, CAS-number, etc.) is informative in order to correctly interpret the results of the questionnaire.</p>
<p>2.22. Rubber chemicals</p>	<p>The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.</p>	<p>Specification of chemicals (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire. Rubber chemicals could contain e.g. various anilines and PAHs, which are 1stpriority substances under HBM4EU. Please, specify the work where you come into contact with rubber chemicals.</p>
<p>2.23. Flame retardants</p>	<p>Flame retardants are 1stpriority substances under HBM4EU.</p>	<p>Specification of flame retardants and their ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire.</p>
<p>2.24. Nanomaterials</p>	<p>The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.</p>	<p>Specification of nanomaterials and nanoparticles (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire.</p>
<p>2.25. Photoresist/antireflective coatings</p>	<p>The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.</p>	<p>Specification of photoresist/antireflective coatings and their ingredients (name, CAS-number, etc.) is essential in order to correctly interpret the results of the questionnaire.</p>

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
<p>2.26. Other hazardous materials, hazardous waste or other chemicals (e.g. contaminated soil renovation)</p>	<p>The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.</p>	<p>Specification of exposure to any other hazardous materials, hazardous waste or other chemicals (name, CAS-number, etc.) is also helpful to correctly interpret the results of the questionnaire. These could include e.g. various chemical mixtures, which are 1stpriority substances under HBM4EU.</p>
<p>2.27. Other compounds</p>	<p>The question is aimed to obtain an overall and complete overview of the participants' exposure conditions in order to correctly interpret the results of the questionnaire and biological monitoring as well as to avoid possible bias.</p>	<p>Specification of exposure to any other compounds (name, CAS-number, etc.) is also helpful to correctly interpret the results of the questionnaire.</p>
<p>3. Were you subjected to a health surveillance program at work in the past?</p> <p>If yes: Did this health surveillance program to which you were subjected include biological monitoring (measurement of chemicals or their metabolites in e.g blood or urine samples)?</p>	<p>This question provides information on whether biological monitoring had been carried out in previous jobs.</p>	<p>If answer is yes: -What chemicals/substances were monitored (if known, please specify the CAS number)? Specification of analyte and biological material (e.g. chromium in urine) is also essential. -How often was biological monitoring carried out?</p>

VI. HEALTH

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
1. Anthropometric measurements	Anthropometric measurements are indicators of body composition. The BMI has been shown to be significantly correlated with exposure to some phthalates.	Record the self-reported height in cm without shoes. Record the self-reported weight in kg without clothes and shoes.
2. Weight change	Weight change is an indicator of intended and unintended changes in body weight.	If the interviewee reports that his/her weight has not changed during the past year, skip questions 2.2 and 2.3. For 2.2 and 2.3 weight change is recorded in kg.
3. Do you have or have you ever had any of the following diseases or conditions, diagnosed by a medical doctor? If yes, please specify how old you were when this was first diagnosed.	The information about diagnosed diseases is an indicator about disease prevalence and disease history.	The interviewee is asked to provide answer to all diseases on the list and if he/she says “Yes”, then ask and record the age when the disease was diagnosed for the first time. If the interviewee says that he/she has been diagnosed for any other disease(s) not listed, this should be recorded at the end under ‘Other diseases or conditions’
4. If you answered “Yes” for cancer, please specify what kind of cancer	The information about cancer types is an indicator of specific cancer prevalence.	This question is asked only for those who self-reported to have or have had any cancer. In case of having had more than one cancer at different sites, record all different cancers reported.
5. During the past two weeks, have you used any medicines that were prescribed for you by a doctor?	This question provides information about medication use for three defined diseases: hypertension, high cholesterol and diabetes. This information is needed, in addition that from health examinations, to define whether a person has hypertension, elevated cholesterol or diabetes.	This question asks use of medication for hypertension, high blood cholesterol levels and diabetes.
5.1 Which medicines prescribed for you by a doctor you have used in the past two weeks? Please, indicate the commercial name of the medicine, the indication, as well as the strength of the drug, dose and frequency of use	This question provides information about medication use in general. This information is needed to define does person have a specific disease together with information about diagnosed diseases.	This question asks about the use of medicines. All medicines prescribed by a doctor and used in the past two weeks should be recorded as accurately as the interviewee recall this information.

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
6. Have you been vaccinated for?	This question provides information about vaccination status.	Replies to all defined vaccinations are required.
7. Are you pregnant at present?	This question provides information about pregnancy status of female participants. It is needed to identify pregnant women as they may need to be treated separately in some analysis.	This question is asked for women only. Question is asked from women younger than 45 years.
8. Have you ever been pregnant?	This question provides information on the number of pregnancies.	This question is asked for women only. If the interviewee replies that she has ever been pregnant, ask the number of pregnancies including possible current pregnancy, live births, miscarriages, stillbirths, tubal pregnancies and abortions.
9. Please, complete the following information for each of your pregnancies	This question provides detailed information on each pregnancy.	This question is asked for women only. For each pregnancy, information is needed about the outcome: abortion, live birth, polyembryotic or birth defects have to be recorded.
10. Are you breast feeding or had breastfed? If so, please indicate the length of breastfeeding.	This question provides information about breast feeding history, since it could affect the concentrations of certain compounds in humans (e.g. PFASs, FR).	This question is asked from women only. Women with several children have to specify total months of breastfeeding.
11. Have there been time period when you have attempted to have a child but have not succeeded or it took over 12 months to succeed?	This question provides information on fertility problems.	This question is asked for women only. This question refers to attempts to get pregnant without success or when it took over 12 months to succeed. If person replies 'Yes', the further question to ask is when was the last time this happened (in years) is asked.
12. Have you ever been examined or been treated for infertility?	This question provides information on fertility problems.	This question is asked for women only.
12.1 What was the reason for your infertility?	This question provides information on type of the fertility problems.	This question is asked for women only. This question refers to the fertility problems listed in the questionnaire.

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
13. Which of the following options best describe your menstrual cycle?	Information on menstrual cycle and menopause will be collected here, since it could affect the bioaccumulation of priority substances in women (e.g. PFASs).	This question is asked from women only. Please, collect information on the current situation. Menopause refers to the absence of menstrual periods for 12 consecutive months
14. Have there been time period when you have attempted to have a child but have not succeeded or it took over 12 months to succeed?	This question provides information about fertility problems.	This question is asked from men only. This question refers to attempts to get pregnant without success or when it took over 12 months to succeed. If person replies 'Yes', further question on when was the last time this happened (in years) is asked.
15. Have you ever been examined or been treated for infertility?	This question provides information regarding fertility problems.	This question is asked from men only. This question refers to attempts to have a child without getting it or when it took over 12 months to succeed. If person replies 'Yes', the further question to ask is when was the last time this happened (in years).
15.1 What was the reason for your infertility?	This question provides information on fertility problems.	This question is asked for men only.
16. Do you have amalgam fillings/dental sealant in your teeth?	This question is used to identify persons with amalgam fillings and dental sealant. They may need to be treated separately in some analysis. Dental sealant is a determinant of exposure to BPA, while amalgam fillings could be a source of exposure to metals.	Please note that a filling is expected to last for as many as ten years, whereas the average life expectancy of a dental sealant is no longer than a year. Sealants are usually provided to children. If person reports that he/she has any amalgam fillings, the number of teeth which have the filling should be recorded as the time when the filling was last time placed/removed.

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
<p>17. Have you done any body modifications? (excluding medical interventions). If yes, specify how long since you got first</p>	<p>This question is used to identify persons with body modifications. They may need to be treated separately in some analysis. Body modifications, such as piercings or tattoos (including different colours), could be a source of exposure to certain metals (e.g. cadmium, chromium) and PAHs.</p>	<p>This question excludes any medical intervention done for the body. Please, specify the colour(s) of the tattoo, when applicable. The timing for each body modification should be reported as accurately as possible. If the number of days cannot be precisely recalled, ask at least for the number of months and years. In case the number of months is difficult to provide, at least the number of years should be recorded.</p>
<p>18. Do you have any artificial joints, pins, plates, metal suture materials, or other types of metal objects in your body? (Do not include piercings, crowns, dental braces or retainers, shrapnel, or bullets.)</p>	<p>This question is used to identify persons with artificial joints etc. in their body. These may need to be treated separately in some analysis.</p>	<p>The interviewee should answer “Yes” if he/she has any of the listed objects in their body.</p>
<p>19. How often do you usually wear metallic jewellery (e.g. rings, earrings, necklaces)</p>	<p>Wearing metallic jewellery on the skin could be a source of exposure to certain metals, specially chromium.</p>	<p>Please, specify here if the interviewee wear metallic jewellery and frequency.</p>
<p>20. Do you use glasses and/or contact eye lenses?</p>	<p>Potential determinant of the exposure to BPA.</p>	<p>Use of glasses or contact lenses has to be collected here.</p>



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HORIZON2020 Programme
Contract No. 733032 HBM4EU

Annex 2.1.2.1

Summary table of ISCED 2011 codes and criteria

WP 7

Task 7.3

D 7.3



Annex A

Summary table of ISCED 2011 codes and criteria

The units of the ISCED classification are education programmes and their related recognised qualifications.

<http://www.uis.unesco.org/Education/Pages/international-standard-classification-of-education.aspx>

The ISCED classification uses **3 digits**: the **first is the educational level**, the **second** and **third are complementary dimensions**.

The ISCED level of an education programme reflects the degree of complexity and specialisation of the content of the programme measured with respect to gradations of learning experiences and the knowledge, skills and competencies the programme is intended to impart. Educational attainment is measured with respect to the highest education programme successfully completed, which is normally certified by a recognised qualification. If the highest education programme is not successfully completed, the level of attainment of the person is their attainment level before entering the programme.

LEVELS AND COMPLEMENTARY DIMENSIONS OF THE INTERNATIONAL STANDARD CLASSIFICATION OF EDUCATION (ISCED) 2011

Codification of education programmes and educational attainment

Level		Criteria for classifying national programmes by levels	
1 st digit		Main criteria	Subsidiary criteria
No education		–	–
0	Early childhood education	<i>Learning stimulated</i> by environment (§105)* or in interaction with educators (§106).	<i>Qualifications of staff:</i> Pedagogical qualifications for educators (§111).
		<i>Institution:</i> school-based or centre-based (§107)	Existence of a regulatory framework (§112).
		<i>Admission/age:</i> 3 years and above for pre-primary education (§102/108).	Typically not compulsory (§113).
		<i>Intensity:</i> 2 hours of education per day and 100 days a year (§110).	
1	Primary education	<i>Education</i> with systematic teaching and learning in reading, writing and mathematics (§125).	Often coincides with the beginning of compulsory education (§127).
		<i>Admission/age and duration:</i> official age of entry between ages 5 and 7 years; typical duration of 6 years (range is 4 to 7 years) (§122).	
		<i>Teacher:</i> typically one main teacher is in charge of a group (§126).	
2	Lower secondary education	<i>Transition to subject-oriented instruction</i> (§144).	<i>Typical entry age</i> is between 10 and 13 years, the most common being 12 (§141).
		<i>Entry requirements:</i> completion of primary education (or the capacity to study at ISCED level 2) (§145).	<i>Subject teachers,</i> with qualifications in specific subjects as well as pedagogy (§147).
		<i>Cumulative duration:</i> ends after 8 to 11 years of education (often 9) from the start of primary education (§146).	The end of the level often coincides with the <i>end of compulsory education</i> (§148).

Notes

* Paragraph numbers are references to the main ISCED 2011 classification document. See more details in the Reader's Guide.

** European Union Labour Force Survey variable HATLEVEL / HATVOC (European Commission Regulation 317/2013).



Complementary dimensions				Coding		
2 nd digit		3 rd digit		Education programmes ISCED-P (Annex II of ISCED 2011)	Educational attainment ISCED-A (Annex III of ISCED 2011)	EU Labour Force Survey variable HATLEVEL/HATVOC**
-		-		-	010	000
Type of education:						
1	Early childhood educational development (0 to 2 years)	-	-	010	020	-
2	Pre-primary education (from 3 years to the start of primary education)	-	-	020		000
-	-	-	-	100	100	100
Programme orientation:			Level completion and access to higher ISCED level:			
4	General	1	Insufficient for level completion or partial level completion (duration < 2 years or cumulative duration < 8 years since the start of ISCED level 1).	241, 251	100	100
		2	Partial level completion (intermediate programme with duration ≥ 2 years and cumulative duration ≥ 8 years).	242, 252	242, 252	200
5	Vocational	3	Level completion without direct access to ISCED 3 (duration ≥ 2 years, cumulative duration ≥ 8 years).	243, 253	243, 253	200
		4	Level completion with direct access to ISCED 3 (duration ≥ 2 years, cumulative duration ≥ 8 years).	244, 254	244, 254	200

Notes

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** European Union Labour Force Survey variable HATLEVEL / HATVOC (European Commission Regulation 317/2013).



Level		Criteria for classifying national programmes by levels	
1 st digit		Main criteria	Subsidiary criteria
3	Upper secondary education	<i>Second/final stage of secondary education, in form of general or vocational programmes (§167).</i>	<i>More differentiated programmes: increased range of options and streams (§169).</i>
		<i>Entry requirements: completion of lower secondary education (or the capacity to study at ISCED level 3) (§168).</i>	<i>Teachers often more qualified with respect to the subject matter they teach than lower secondary teachers (§170).</i>
		<i>Cumulative duration: programmes end 12 or 13 years since the beginning of ISCED 1 (§164).</i>	
4	Post-secondary non-tertiary education	<i>Post-secondary education, generally vocational and terminal programmes preparing for the labour market; typically, not considered as tertiary education at the national level (§190).</i>	
		<i>Programmes which serve to broaden rather than deepen the knowledge, skills and competencies of participants. Often not significantly more advanced than programmes at ISCED level 3 (§191).</i>	
		<i>Entry requirements: completion of upper secondary education (§186).</i>	
5	Short-cycle tertiary education	<i>Programmes often designed to provide participants with professional knowledge, skills and competencies; may provide pathway to academic programmes (§207). More complex than levels 3 and 4 but less than 6 (§212).</i>	<i>Institutional transition points: often provided by different institutions from ISCED levels 6, 7 and 8 (§214).</i>
		<i>Entry requirements: successful completion of upper secondary or post-secondary non-tertiary education giving access to ISCED levels 5, 6 or 7 (§208)</i>	
		<i>Minimum duration: 2 years (§213).</i>	<i>Typical duration: 2 to 3 years (§213).</i>

Notes

* Paragraph numbers are references to the main ISCED 2011 classification document. See more details in the Reader's Guide.

** European Union Labour Force Survey variable HATLEVEL / HATVOC (European Commission Regulation 317/2013).



Complementary dimensions			Coding			
2 nd digit	3 rd digit		Education programmes ISCED-P (Annex II of ISCED 2011)	Educational attainment ISCED-A (Annex III of ISCED 2011)	EU Labour Force Survey variable HATLEVEL/HATVOC**	
Programme orientation:		Level completion and access to higher ISCED level:				
4	General	1	Insufficient for level completion or partial level completion (duration < 2 years or cumulative duration < 11 years since the start of ISCED level 1).	341, 351	244, 254	200
		2	Partial level completion (intermediate programme with duration ≥ 2 years and cumulative duration ≥ 11 years).	342, 352	342, 352	302/1, 302/2
5	Vocational	3	Level completion without direct access to ISCED 3 (duration ≥ 2 years, cumulative duration ≥ 11 years).	343, 353	343, 353	303/1, 303/2
		4	Level completion with direct access to ISCED 5, 6 or 7 (duration ≥ 2 years, cumulative duration ≥ 11 years).	344, 354	344, 354	304/1, 304/2
Programme orientation:		Level completion and access to higher ISCED level:				
4	General	1	Insufficient for level completion (duration < 6 months)	441, 451	344 354	300/1, 300/2
5	Vocational	3	Level completion without direct access to ISCED 5, 6 or 7	443, 453	443, 453	400/1, 400/2
		4	Level completion with direct access to ISCED 5, 6 or 7	444, 454	444, 454	
Programme orientation:		Level completion and access to higher ISCED level:				
4	General (or academic)	1	Insufficient for level completion (duration < 2 years)	541, 551	444, 454	400
5	Vocational (or professional)	4	Level completion	544, 554	540, 550	500

Notes

* Paragraph numbers are references to the main ISCED 2011 classification document. See more details in the Reader's Guide.

** European Union Labour Force Survey variable HATLEVEL / HATVOC (European Commission Regulation 317/2013).



Level		Criteria for classifying national programmes by levels	
1 st digit		Main criteria	Subsidiary criteria
6	Bachelor's or equivalent	Programmes often designed to provide participants with intermediate academic or professional knowledge, skills and competencies, leading to a first degree, such as a <i>Bachelor's</i> , or to an equivalent qualification (§224).	The requirement of a doctorate (ISCED level 8) qualification for some of the teaching staff may help distinguish ISCED levels 5 and 6 (§231).
		<i>Entry requirements:</i> successful completion of upper secondary or post-secondary non-tertiary education giving access to ISCED levels 5, 6 or 7; may require the passing of an entrance examination (§226).	<i>Further studies:</i> does not give direct access (usually) to doctoral programmes (ISCED level 8) (§226).
		<i>Minimum cumulative duration of first degrees:</i> 3 to 4 years full-time (§229).	
		<i>Position in the national degree structure:</i> typically a first degree in tertiary education; sometimes a second degree of 1 to 2 years (§230).	
7	Master's or equivalent	Programmes often designed to provide participants with advanced academic or professional knowledge, skills and competencies, leading to a second degree, such as a <i>Master's</i> , or to an equivalent qualification (§241).	<i>Minimum duration of long 1st degree:</i> 5 years; complexity of content comparable to a <i>Master's</i> (§247).
		<i>Position in the national degree structure:</i> typically a second or further degree in tertiary education following a first degree at ISCED level 6 or 7 (§246) or a long first degree of at least 5 years if equivalent to a <i>Master's</i> in terms of the complexity of content (e.g. medicine) (§247).	<i>Further studies:</i> often gives direct access to doctoral programmes (ISCED level 8) (§249).
		<i>Entry requirements:</i> in the case of a 2 nd degree, the successful completion of a <i>Bachelor's</i> or equivalent (ISCED level 6) or a <i>Master's</i> or equivalent (ISCED level 7) is required; in the case of a 1 st degree, the successful completion of upper secondary or of ISCED 4 granting access to tertiary education is required and, eventually, an entry examination (§243).	
8	Doctoral or equivalent	Its successful completion requires the <i>submission of a thesis</i> or an equivalent written work, of publishable quality, which is the output of original research representing a considerable contribution to knowledge in the field (§264).	Degree gives access to faculty positions and research posts (§266).
		<i>Entry requirements:</i> the successful completion of an ISCED 7 programme (§261).	
		<i>Minimum duration:</i> at least 3 years of full-time studies and a total cumulative duration of at least 7 years of tertiary education (§265)	

Notes

* Paragraph numbers are references to the main ISCED 2011 classification document. See more details in the Reader's Guide.

** European Union Labour Force Survey variable HATLEVEL / HATVOC (European Commission Regulation 317/2013).

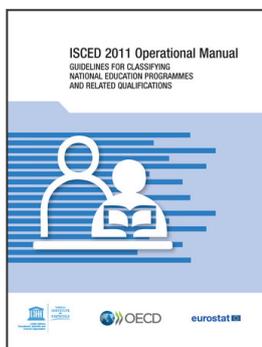


Complementary dimensions				Coding		
2 nd digit		3 rd digit		Education programmes ISCED-P (Annex II of ISCED 2011)	Educational attainment ISCED-A (Annex III of ISCED 2011)	EU Labour Force Survey variable HATLEVEL/HATVOC**
Programme orientation:		Position in the national degree and qualification structure:				
4	Academic	1	Insufficient for level completion (duration of first degree < 3 years)	641, 651, 661	540, 550	500
5	Professional	5	First degree (at Bachelor's level) (duration 3 to 4 years)	645, 655, 665	640, 650, 660	600
6	Unspecified	6	Long first degree (at Bachelor's level) (duration > 4 years)	646, 656, 666		
		7	Second or further degree (following a 1 st degree at Bachelor's level)	647, 657, 667		
Programme orientation:		Position in the national degree and qualification structure:				
4	Academic	1	Insufficient for level completion (duration of first degree < 5 years)	741, 751, 761	640, 650, 660	600
5	Professional	6	Long first degree (at Master's level) (duration ≥ 5 years)	746, 756, 766	740, 750, 760	700
6	Unspecified	7	Second or further degree (following a 1 st degree at Bachelor's level)	747, 757, 767		
		8	Second or further degree (following a 1 st degree at Master's level)	748, 758, 768		
Programme orientation:		Position in the national degree and qualification structure:				
4	Academic	1	Insufficient for level completion (duration of first degree < 3 years)	841, 851, 861	740, 750, 760	700
5	Professional	4	Level completion	844, 854, 864	840, 850, 860	800
6	Unspecified					

Notes

* Paragraph numbers are references to the main ISCED 2011 classification document. See more details in the Reader's Guide.

** European Union Labour Force Survey variable HATLEVEL / HATVOC (European Commission Regulation 317/2013).



From:

ISCED 2011 Operational Manual

Guidelines for Classifying National Education Programmes and Related Qualifications

Access the complete publication at:

<http://dx.doi.org/10.1787/9789264228368-en>

Please cite this chapter as:

OECD/Eurostat/UNESCO Institute for Statistics (2015), "Summary table of ISCED 2011 codes and criteria", in *ISCED 2011 Operational Manual: Guidelines for Classifying National Education Programmes and Related Qualifications*, OECD Publishing, Paris.

DOI: <http://dx.doi.org/10.1787/9789264228368-14-en>

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Annex 2.1.2.2

**Definitions of major groups, sub-major groups,
ISCO 2008
WP 7
Task 7.3
D 7.3**

**STRUCTURE OF THE INTERNATIONAL
STANDARD CLASSIFICATION OF
OCCUPATIONS (ISCO-08)**

Major Groups

- 1 Managers
- 2 Professionals
- 3 Technicians and Associate Professionals
- 4 Clerical Support Workers
- 5 Services and Sales Workers
- 6 Skilled Agricultural, Forestry and Fishery Workers
- 7 Craft and Related Trades Workers
- 8 Plant and Machine Operators and Assemblers
- 9 Elementary Occupations
- 0 Armed Forces Occupations

MAJOR AND SUB-MAJOR GROUPS

1 Managers

- 11 Chief Executives, Senior Officials and Legislators
- 12 Administrative and Commercial Managers
- 13 Production and Specialized Services Managers
- 14 Hospitality, Retail and Other Services Managers

2 Professionals

- 21 Science and Engineering Professionals
- 22 Health Professionals
- 23 Teaching Professionals
- 24 Business and Administration Professionals
- 25 Information and Communications Technology Professionals
- 26 Legal, Social and Cultural Professionals

3 Technicians and Associate Professionals

- 31 Science and Engineering Associate Professionals
- 32 Health Associate Professionals
- 33 Business and Administration Associate Professionals
- 34 Legal, Social, Cultural and Related Associate Professionals
- 35 Information and Communications Technicians

4 Clerical Support Workers

- 41 General and Keyboard Clerks
- 42 Customer Services Clerks
- 43 Numerical and Material Recording Clerks
- 44 Other Clerical Support Workers

5 Services and Sales Workers

- 51 Personal Services Workers
- 52 Sales Workers
- 53 Personal Care Workers
- 54 Protective Services Workers

6 Skilled Agricultural, Forestry and Fishery Workers

- 61 Market-oriented Skilled Agricultural Workers
- 62 Market-oriented Skilled Forestry, Fishery and Hunting Workers
- 63 Subsistence Farmers, Fishers, Hunters and Gatherers

7 Craft and Related Trades Workers

71 Building and Related Trades Workers (excluding Electricians)

72 Metal, Machinery and Related Trades Workers

73 Handicraft and Printing Workers

74 Electrical and Electronic Trades Workers

75 Food Processing, Woodworking, Garment and Other Craft and Related Trades Workers

8 Plant and Machine Operators and Assemblers

81 Stationary Plant and Machine Operators

82 Assemblers

83 Drivers and Mobile Plant Operators

9 Elementary Occupations

91 Cleaners and Helpers

92 Agricultural, Forestry and Fishery Labourers

93 Labourers in Mining, Construction, Manufacturing and Transport

94 Food Preparation Assistants

95 Street and Related Sales and Services Workers

96 Refuse Workers and Other Elementary Workers

0 Armed Forces Occupations

01 Commissioned Armed Forces Officers

02 Non-commissioned Armed Forces Officers

03 Armed Forces Occupations, Other Ranks



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Annex 2.1.2.3

Food serving sizes gallery

WP 7

Task 7.3

D 7.3

ANNEX 2.1.2.3 FOOD SERVING SIZES GALLERY

Pictures included in this gallery will be used to answer food consumption frequency questionnaire. These pictures will help to collect accurate measurements of serving sizes consumed by the participants. Please, indicate the number of servings of each food item consumed in the last 4 weeks, according to the relationship with the food picture.

I. FISH

WHITE FISH



Serving: two medium units (125 g)



Serving: one medium unit (130 g)

BLUE FISH (BIG SIZE)



Serving: one unit (steak, 125 g)

BLUE FISH (SMALL SIZE)



Serving: 10-15 units (225 g)



Serving: 4 units (250 g)

SALMON



Serving: one piece (130 g)

CEPHALOPODS (e.g squid, octopus)



Serving: one médium unit (100 g)

TINNED FISH



Serving: one can (60 g)

FISH FINGERS



Serving: 4 units (100 g)

CRUSTACEANS AND SHELLFISH (lobster, crayfish, scampi, crab, prawns, oysters, mussels, ...)



Serving: 15 units (100 g)



Serving: 15 units (200 g)

II. MEAT

WHITE MEAT (poultry, turkey etc...)



Serving: one thigh (290 g)



Serving: 4 units (100 g)

RED MEAT (pork, beef)



Serving: one unit (100 g)



Serving: 4 units (100 g)



Serving: one unit (90-100 g)



Serving: 2 units (100 g)

III. DAIRY PRODUCTS (NOT SKIMMED) AND EGGS

BUTTER



Serving: oneteaspoon (10 g)

MILK



Serving: one medium glass (200 ml)

CHEESE



Serving: 3 units (40 g)



Serving: 2 units (40 g)

YOGURT AND SIMILARS



Serving: one unit (125 g)



Serving: one unit (125 g)

EGGS



Serving: 2 units (120 g)

IV. CEREALS

Bread (White and Whole grain)



Serving: 2 units (100 g)

Cereal products (crackers, rusk, etc...)



Serving: 3 units (40 g)



Serving: half commercial packet(50 g)

OTHER CEREALS



Serving: 2 handfuls (30 g)



Serving: 2 handfuls (30 g)



Serving: one unit (25 g)

PASTA



Serving: half a coffee cup (75 g)



Serving: 75 g

RICE



Serving: half a coffee cup (75 g)

FATS



V. VEGETABLES AND FRUITS

CARROTS



Serving: 2 units (200 g)

FRESH TOMATOES



Serving: 2 units (200 g)

LEAFY VEGETABLES



Serving: 4 handfuls (200 g)



Serving: 10 units (200 g)

BROCCOLI



Serving: 1/3 unit (200 g)

GREEN BEANS



Serving: 10-15 units (200 g)

CHIPS/FRENCH FRIES



Serving: 100 g

MUSHROOMS



Serving: 8 units (200 g)

ONION



Serving: one unit (200-250 g)

SOYBEANS



Serving: one handful (20 g)

TINNED PRODUCTS (e.g. vegetables, legumes, cereals)



Serving: one can (150 g)



Serving: 9 units (200 g)

FRESH FRUITS



Serving: one unit (150-200 g)



Serving: one slice (150-170g)



Serving: one slice (200 g)



Serving: 5-7 units (200 g)

FRUIT JUICES



Serving: one glass or individual brick (200 ml)

VI. SNACKS

Popcorn (microwave or home-made)



Serving: one bowl (30 g)

PEANUTS



Serving: 2 tablespoons (30 g)

ICECREAMS



Serving: one unit (75 g)



Serving: one piece (two fingers thick, 60 g or 100 ml)

POTATO CHIPS



Serving: one bowl (50 g)

JELLY CANDIES



Serving: 20 units (30 g)

HAZELNUT SPREAD



Serving: one tablespoon (20-30 g)

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Pictures and information of this gallery are online available at: <http://www.insidemyfood.com>

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Annex 2.1.2.4

**The Statistical classification of economic activities in
the European Community, abbreviated as NACE (Type
of industry/workplace)**

WP 7

Task 7.3

D 7.3

ANNEX 2.1.2.4 Type of industry/workplace

A – Agriculture, forestry and fishing;

- 01 Crop and animal production, hunting and related service activities
- 02 Forestry and logging
- 03 Fishing and aquaculture

B – Mining and quarrying;

- 05 Mining of coal and lignite
- 06 Extraction of crude petroleum and natural gas
- 07 Mining of metal ores
- 08 Other mining and quarrying
- 09 Mining support service activities

C – Manufacturing;

- 10 Manufacture of food products
- 11 Manufacture of beverages
- 12 Manufacture of tobacco products
- 13 Manufacture of textiles
- 14 Manufacture of wearing apparel
- 15 Manufacture of leather and related products
- 16 Manufacture of wood and of products of wood and cork, except furniture; manufacture of particles of straw and plaiting materials
- 17 Manufacture of paper and paper products
- 18 Printing and reproduction of recorded media
- 19 Manufacture of coke and refined petroleum products
- 20 Manufacture of chemicals and chemical products
- 21 Manufacture of basic pharmaceutical products and pharmaceutical preparations
- 22 Manufacture of rubber and plastic products
- 23 Manufacture of other non-metallic mineral products
- 24 Manufacture of basic metals
- 25 Manufacture of fabricated metal products, except machinery and equipment
- 26 Manufacture of computer, electronic and optical products
- 27 Manufacture of electrical equipment
- 28 Manufacture of machinery and equipment n.e.c.
- 29 Manufacture of motor vehicles, trailers and semi-trailers
- 30 Manufacture of other transport equipment

- 31 Manufacture of furniture
- 32 Other manufacturing
- 33 Repair and installation of machinery and equipment
- D – Electricity, gas, steam and air conditioning supply;**
- 35 Electricity, gas, steam and air conditioning supply

- E – Water supply, sewerage, waste management and remediation activities;**
- 36 Water collection, treatment and supply
- 37 Sewerage
- 38 Waste collection, treatment and disposal activities; materials recovery
- 39 Remediation activities and other waste management services

- F – Construction;**
- 41 Construction of buildings
- 42 Civil engineering
- 43 Specialised construction activities

- G – Wholesale and retail trade, repair of motor vehicle and motorcycles;**
- 45 Wholesale and retail trade and repair of motor vehicles and motorcycles
- 46 Wholesale trade, except of motor vehicles and motorcycles
- 47 Retail trade, except of motor vehicles and motorcycles

- H – Transportation and storage;**
- 49 Land transport and transport via pipelines
- 50 Water transport
- 51 Air transport
- 52 Warehousing and support activities for transportation
- 53 Postal and courier activities

- I – Accommodation and food service activities;**
- 55 Accommodation
- 56 Food and beverage service activities

- J – Information and communication;**
- 58 Publishing activities
- 59 Motion picture, video and television programme production, sound recording and music publishing activities
- 60 Programming and broadcasting activities
- 61 Telecommunications
- 62 Computer programming, consultancy and related activities
- 63 Information service activities

- K – Financial and insurance activities;**
- 64 Financial service activities, except insurance and pension funding
 - 65 Insurance, reinsurance and pension funding, except compulsory social security
 - 66 Activities auxiliary to financial services and insurance activities
- L – Real estate activities;**
- 68 Real estate activities
- M – Professional, scientific and technical activities;**
- 69 Legal and accounting activities
 - 70 Activities of head offices; management consultancy activities
 - 71 Architectural and engineering activities; technical testing and analysis
 - 72 Scientific research and development
 - 73 Advertising and market research
 - 74 Other professional, scientific and technical activities
 - 75 Veterinary activities
- N – Administrative and support service activities;**
- 77 Rental and leasing activities
 - 78 Employment activities
 - 79 Travel agency, tour operator and other reservation service and related activities
 - 80 Security and investigation activities
 - 81 Services to buildings and landscape activities
 - 82 Office administrative, office support and other business support activities
- O – Public administration and defence, compulsory social security;**
- 84 Public administration and defence; compulsory social security
- P – Education;**
- 85 Education
- Q – Human health and social work activities;**
- 86 Human health activities
 - 87 Residential care activities
 - 88 Social work activities without accommodation
- R – Arts, entertainment and recreation;**
- 90 Creative, arts and entertainment activities
 - 91 Libraries, archives, museums and other cultural activities
 - 92 Gambling and betting activities
 - 93 Sports activities and amusement and recreation activities

S – Other service activities;

94 Activities of membership organisations

95 Repair of computers and personal and household goods

96 Other personal service activities

T – Activities of households as employers, undifferentiated goods – and services – producing activities of households for own use;

97 Activities of households as employers of domestic personnel

98 Undifferentiated goods- and services-producing activities of private households for own use

U – Activities of extraterritorial organisations and bodies.

99 Activities of extraterritorial organisations and bodies



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Annex 2.1.3

**Matrix-specific questionnaires to accompany the
sampling of urine and blood**

WP 7

Task 7.3

D7.3

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Many thanks to Christine Schulz (UBA) who shared valuable experience from the past and current German Environmental Surveys!

This document has been created for the HBM4EU project. HBM4EU has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733032.

1 Introduction and Aims

When evaluating human samples for exposure with certain substances or substance groups, it can prove useful in some cases to have information available about potential exposure sources of the sample provider directly prior to the point in time where the sample was taken. This means that the questionnaires accompanying the sampling of a matrix (or matrix-specific questionnaires) specifically aim to mostly cover substances with a short half-life.

This difference to the basic questionnaire should be explicitly explained and continuously stressed to the interviewer staff during training.

The HBM4EU matrix-specific questionnaires have been designed to collect a select amount of information concerning individual characteristics of the participants and on different sources and routes of exposure to the 1st-priority substances selected for study (Phthalates/DINCH, Bisphenols, Per-/Polyfluorinated compounds, Flame Retardants, Cd, Cr, PAHs and Aniline family: MOCA), with the aim to characterise as well as possible the level of exposure to these substances (where considered relevant) directly prior (past 24 or 48 hours) to the sampling.

As urine and blood are currently the most likely matrices to be analysed, questionnaires have been prepared accordingly. It might be necessary to adapt some wording and use specific questions in the urine questionnaire depending on the type of urine envisioned to be sampled (e.g. morning urine, spot urine, etc.).

Furthermore, questions might need to be adjusted or taken out according to the individual study design, e.g. in case there is only one label on the sample container, the questions pertaining to the labelling need to be merged.

Specific testing of these questionnaires in a subsample of a population still needs to be undertaken. It could be feasible to perform testing with representatives (or a subsample) of the envisaged group of participants right before a study using this questionnaire is conducted.

2 Questionnaire accompanying the sampling of urine

In the following, the questionnaire accompanying the sampling of urine is presented.

The notes under Section 2.1 are important to consider when applying the questionnaire. The accompanying Interviewer Manual can be used to learn about the background of questions, the substance groups of interest in each question as well as specific notes and advice for the application of the questions.

QUESTIONNAIRE TO ACCOMPANY THE SAMPLING OF URINE (1st PRIORITY SUBSTANCES)

QUESTIONNAIRE INFORMATION

ID (PARTICIPANT)	_ _ _ _ _ _ _
ID (INTERVIEWER)	_ _ _ _ _ _ _
DATE OF THE INTERVIEW	_ _ _ _ _ _ _ _ _
START TIME	_ _ : _ _
END TIME	_ _ : _ _
PLACE	



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733032.

2.1 Notes

Questions with a white background are to be addressed to and answered by the participant.

Questions with a grey background are to be answered by the interviewer or the study centre and should not be addressed directly to the participant.

Questions with a light green background are to be asked only when first morning urine is collected.

Questions with a light red background **only have to be asked if (a) urine sampling is not foreseen** in the survey **or** if (b) blood and urine sampling did not happen at the same time (**> 1 h between sampling of blood and sampling of urine**).

2.2 General questions regarding the sample itself

U1 Has the [first morning] urine sample been delivered?

Yes Please continue with question 2.

No Please indicate the reason for missing submission of the morning urine sample below:

a) Sampling was forgotten in the morning [if foreseen: another appointment can be made now]

b) Sampling container not available [if foreseen: another appointment can be made now]

c) No consent

d) Other reason, that being: _____

U2 Was the urine sample collected in the provided container?

Yes

No ► [It should be decided by the study owner if the sample will be discharged or kept. This information should be recorded.]

Questions U3 and U4 can be merged if it is foreseen to use only one label:

U3 Is there a sampling label on the container?

Yes

No ► Please add one to the container now.

U4 Is there a label with the correct participant ID on the container?

Interviewer: Please cross-check label and title pages of all questionnaires asked.

Yes

No ► Please add one to the container now.

U5 When was the [morning] urine sample obtained?

Interviewer: Ask participant or copy from sampling label if this information is included. Please check the information for plausibility! If the date is different to the date of the home visit, please note this down. The sample might have to be discarded.

on 20 at : hrs
 Day Month Year Hour Minute

U6 Is it really the first urine after waking up?

Interviewer: If the time of the sampling is not in the hours of the morning, meaning up to a max. 12 pm, ask the participant(s) whether this time is correct and whether it is really the first urine after waking up.

Yes

No [It should be decided by the study owner if the sample will be discharged or kept. This information should be recorded.]

Don't know ► [It should be decided by the study owner if the sample will be discharged or kept. This information should be recorded.]

Refused ► [It should be decided by the study owner if the sample will be discharged or kept. This information should be recorded.]

U7 When was your last meal before urine sample collection?

Interviewer: Please consider also small snacks like fruit and sweets.

on 20 at : hrs
 Day Month Year Hour Minute

U8 When did you last urinate before urine sample collection?

Interviewer: Ask participant or copy from sampling label if this information is included. Please check the information for plausibility!

on 20 at : hrs
 Day Month Year Hour Minute

Don't know Refused

U9 According to your information, the last visit to the toilet was at least 4 hours before sampling!

Interviewer: Check whether this is plausible and if not, ask all information again.

Yes

No ► [It should be decided by the study owner if the sample will be discharged or kept. This information should be recorded.]

U10 How was the sample stored at home before collection?

Refrigerator

Other cool place

Non-chilled

Don't know Refused

U11 should only be included if the study is foreseen to use containers big enough to collect all morning urine:

U11 Is the morning urine sample complete? Complete means that all morning urine was collected for the urine sample!

Yes

No Please indicate the reason for incomplete morning urine sample:

- a) Forgot that all morning urine is collected [if foreseen: another appointment can be made now]
- b) Something went wrong [if foreseen: another appointment can be made now]
- c) The collection container was too small
- d) Other reason, that being: _____

Don't know Refused

2.3 Residential environment and home exposures

U12 Have you been outdoors (walking, cycling, etc.) next to a street with constant traffic during the 24 hours prior to sampling?

No Please continue with question U13.

Yes ► Go to question U12a.

U12a How long in total have you been outdoors (walking, cycling, etc.) next to a street with constant traffic during the 24 hours prior to sampling?

- a) Less than 30 minutes
- b) Between 30 minutes and 1 hour
- c) Between 1 and 4 hours
- d) More than 4 hours

Don't know Refused

U13 Have you inhaled smoke from the following energy sources inside your home during the 24 hrs prior to sampling?

Gas

Charcoal/Coal

Wood (firewood, chips, pellets, etc.)

Don't know Refused

Jelly candies	<input type="checkbox"/>					
Smoked food (e.g. ham, smoked pork, smoked cheese, Frankfurters)	<input type="checkbox"/>					
Grilled food (over open flame / burning embers)	<input type="checkbox"/>					
Fried food	<input type="checkbox"/>					
Toasted bread	<input type="checkbox"/>					
Fast food	<input type="checkbox"/>					
Canned food	<input type="checkbox"/>					
Ready meals (in plastic packaging)	<input type="checkbox"/>					
					Refused	<input type="checkbox"/>

U15 During the past 24 hrs prior to sampling, did you drink beverages from any of the following materials?

Interviewer: It is possible to tick more than one box in the list below. All beverages are asked for, including water, hot drinks and alcoholic drinks.

- | | |
|-------------------|--------------------------|
| Glass bottle | <input type="checkbox"/> |
| Plastic bottle | <input type="checkbox"/> |
| Can | <input type="checkbox"/> |
| Plastic mug | <input type="checkbox"/> |
| Plastic glass | <input type="checkbox"/> |
| Polystyrene | <input type="checkbox"/> |
| Cardboard | <input type="checkbox"/> |
| None of the above | <input type="checkbox"/> |

U16 Before providing the sample, when did you last drink any beverages belonging to the following list?

	Not at all	Less than 12 hours	Between 12 and 24 hours	Between 24 and 48 hours	More than 48 hours ago	Don't know
Sakè	<input type="checkbox"/>					
Beer	<input type="checkbox"/>					
Red wine	<input type="checkbox"/>					
Barley coffee	<input type="checkbox"/>					
Juice (vegetable or fruit)	<input type="checkbox"/>					
Whole milk	<input type="checkbox"/>					
					Refused	<input type="checkbox"/>

U17 Did you eat fast food in the past 24 hrs prior to sampling?

Interviewer: Fast foods are processed foods that are easily prepared and served quickly in snack bars and restaurants, typically packed to be 'to-go'.

No Please continue with question U18.

Yes ► Go to question U17a.

U17a How was the fast food packed that you ate during the past 24 hrs prior to sampling?

Interviewer: It is possible to tick more than one box in the list below.

- a) No convenience food at all
- a) In cardboard box
- b) In paper (e.g. bag, box, cup)
- c) In plastic (e.g. bag, box, cup)
- d) In polystyrene foam (e.g. box, cup)
- e) In aluminium container (e.g. canned food)

2.5 Lifestyles

U18 Have you been exposed to tobacco smoke during the 24 hrs prior to sampling?

No

Yes, I have smoked Please continue with question U18a.

Yes, I have been exposed to second hand smoke (passive smoking) Please continue with question U18b.

U18a How many cigarettes during the 24 hrs prior to sampling?

1-5

6-10

11 or more

Refused

U18b How long have you been exposed to second hand smoking during the 24 hrs prior to sampling?

Less than an hour

More than 1 hour

More than 4 hours

Body care products (e.g. body lotion, perfume, shower gel, deodorant)	<input type="checkbox"/>					
Sun cream (sunscreen)	<input type="checkbox"/>					
					Refused	<input type="checkbox"/>

U22 Did you take any of the following types of medication during the past 24 hrs prior to sampling?

	Not at all	Less than 5 hours	Between 5 and 12 hours	Between 12 and 24 hours	Don't know
Paracetamol (analgesic)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Any medication in pill or capsule form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
					Refused <input type="checkbox"/>

U23 During the past 24 hrs prior to sampling, did you undergo one or more of the following medical treatments?

Donated blood

Dialysis

Don't know Refused

U24 In the past 24 hrs prior to sampling, did you put things made out of plastic material (e.g. pens, toys) in your mouth to chew on?

Yes

No

Don't know Refused

in glass jars with
metal lids

Refused

2.8 Any other questions

U28 Were there any peculiarities with the sample or participant's answers?

No

Yes which ones? _____

Don't know Refused

3 Questionnaire accompanying the sampling of blood

In the following, the questionnaire accompanying the sampling of blood is presented.

The notes under Section 3.1 are important to consider when applying the questionnaire. The accompanying Interviewer Manual can be used to learn about the background of questions, the substance groups of interest in each question as well as specific notes and advice for the application of the questions.

QUESTIONNAIRE TO ACCOMPANY THE SAMPLING OF BLOOD (1st PRIORITY SUBSTANCES)

QUESTIONNAIRE INFORMATION	
ID (PARTICIPANT)	_ _ _ _ _ _ _
ID (INTERVIEWER)	_ _ _ _ _ _ _
DATE OF THE INTERVIEW	_ _ _ _ _ _ _ _ _ _ _ _
START TIME	_ _ : _ _
END TIME	_ _ : _ _
PLACE	



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733032.

3.1 Notes

Questions with a white background are to be addressed to and answered by the participant.

Questions with a grey background are to be answered by the interviewer or the study centre and should not be addressed directly to the participant.

Questions with a light green background are to be asked only when first morning urine is collected.

Questions with a light red background **only have to be asked if (a) urine sampling is not foreseen** in the survey **or** if (b) blood and urine sampling did not happen at the same time (**> 1 h between sampling of blood and sampling of urine**).

3.2 General questions regarding the sample itself

B1 Has the blood sample been taken?

Yes

No Please indicate the reason for missing submission of the blood sample below:

a) Sampling was spontaneously refused

b) Unsuccessful puncture

c) No consent

d) Other reason, that being: _____

B2 When was the blood sample obtained?

on 20 at : hrs
Day Month Year Hour Minute

B3 When was your last meal before blood sample collection?

Interviewer: Please consider also small snacks like fruit and sweets.

on 20 at : hrs
Day Month Year Hour Minute

B4 What total amount was sampled?

Gross volume: . mL

B5 If the gross volume was taken in sub-samples: How many sub-samples were taken?

	Amount	Volume taken in each sub-sample
Small tubes	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mL
Large tubes	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mL

Questions B6 and B7 can be merged if it is only foreseen to use one label

B6 Is there a sampling label on the container?

Yes

No Please add one to the container now.

B7 Is there a label with the correct participant ID on the container?

Interviewer: Please cross-check label and title pages of all questionnaires asked.

Yes

No Please add one to the container now.

3.3 Dietary habits

If the participant has not eaten in the past 48 hrs (see response to B3 and B3a), B9 can be skipped.

B9 Before providing the sample, when did you last eat any food belonging to the following food groups?

	Not at all	Less than 12 hours	Between 12 and 24 hours	Between 24 and 48 hours	More than 48 hours ago	Don't know
Fish and seafood (e.g. salmon, tuna, snapper, crustaceans like lobster, shellfish like oysters, mussels etc.)	<input type="checkbox"/>					
Meat (e.g. white and red meat, game, offal)	<input type="checkbox"/>					
Eggs	<input type="checkbox"/>					
Cereals (e.g. bread, crackers, grains, pasta, rice)	<input type="checkbox"/>					
Vegetables (e.g. basil, potatoes, carrots, leafy vegetables)	<input type="checkbox"/>					
Fruit (e.g. basil, potatoes, carrots, fresh tomatoes, leafy vegetables)	<input type="checkbox"/>					
Popcorn (microwave)	<input type="checkbox"/>					
Popcorn (home-made)	<input type="checkbox"/>					
Peanuts	<input type="checkbox"/>					
Canned food	<input type="checkbox"/>					
					Refused	<input type="checkbox"/>

B10 During the past 24 hrs prior to sampling, did you drink beverages from any of the following materials?

Interviewer: It is possible to tick more than one box in the list below. All beverages are asked for, including water, hot drinks and alcoholic drinks.

- e) Plastic bottle
- f) Can
- g) Plastic mug
- h) Plastic glass
- i) None of the above

If the participant has not eaten in the past 48 hrs (see response to B3 and B3a), B11 can be skipped.

B11 When was the last time you ate dishes from communal catering such as from a canteen, dining hall or cafeteria (e.g. at nursery, school or at work/training pace) prior to providing the blood sample?

- | Yesterday (1 day ago) | The day before yesterday (2 days ago) | More than 2 days ago or Never | Don't know |
|--------------------------|---------------------------------------|----------------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | Refused <input type="checkbox"/> | |

B12 Before providing the sample, when did you last drink any beverages belonging to the following list?

	Not at all	Less than 12 hours	Between 12 and 24 hours	Between 24 and 48 hours	More than 48 hours ago	Don't know
Sakè	<input type="checkbox"/>	<input type="checkbox"/>				
Beer	<input type="checkbox"/>	<input type="checkbox"/>				
Red wine	<input type="checkbox"/>	<input type="checkbox"/>				
Barley coffee	<input type="checkbox"/>	<input type="checkbox"/>				
Juice (vegetable or fruit)	<input type="checkbox"/>	<input type="checkbox"/>				
Whole milk	<input type="checkbox"/>	<input type="checkbox"/>				
					Refused <input type="checkbox"/>	

B13a Did you wear personal protection equipment (e.g. a facemask) during one or more of the above-mentioned activities?

Yes

No

Refused

B14 When did you last use any of the following personal care products in the past 48 hours prior to sampling?

	Not at all	Less than 12 hours	Between 12 and 24 hours	Between 24 and 48 hours	More than 48 hours ago	Don't know
Cosmetics (e.g. make-up, nail polish)	<input type="checkbox"/>					
Sun cream (sunscreen)	<input type="checkbox"/>					
					Refused	<input type="checkbox"/>

3.5 Important when toddlers or young children (up to 4 years) are the target group

B15 Did you use any of the following toddler foods during the 24 hrs prior to sampling?

	Not at all	Less than 5 hours	Between 5 and 12 hours	Between 12 and 24 hours	More than 24 hours ago	Don't know
Liquid milk formula (ready to feed)	<input type="checkbox"/>					
Liquid milk formula (concentrate)	<input type="checkbox"/>					
Toddler foods (desserts, fruits, meats, vegetables) in glass jars with metal lids	<input type="checkbox"/>					
				Refused	<input type="checkbox"/>	

3.6 Any other questions

B16 Were there any peculiarities with the sample or participant's answers?
No <input type="checkbox"/>
Yes <input type="checkbox"/> which ones? _____
Don't know <input type="checkbox"/> Refused <input type="checkbox"/>



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Annex 2.1.4

Interviewer Manual to the matrix-specific questionnaires (sampling of urine and blood)

WP 7

Task 7.3

D7.3

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This document has been created for the HBM4EU project. HBM4EU has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733032.

1 General information for the interviewer:

- ▶ For all questions requesting to enter a date, please make sure to enter 24:00 h for the "old" day and 0:00 h for the "new" day.
- ▶ Please keep in mind that most of the questions are aimed at the time before sampling. This is one of the aims of this questionnaire: to find out what the participant did directly prior to providing the sample.
Please check if the participant, when answering the questions, has this in mind. It can be helpful to keep reminding the participant gently that this question is directed at the time before sampling. If necessary, give an example like '24 hrs ago is not yesterday around this time now, but yesterday around the time you provided the sample.'
- ▶ Some questions are present in both blood and urine sampling questionnaires (different numbers are indicated in the table below). Questions with red background light red background only have to be asked if (a) urine sampling is not foreseen in the survey or if (b) blood and urine sampling did not happen at the same time (> 1 h between sampling of blood and sampling of urine).

In the questionnaire:

Questions with a white background are to be addressed to and answered by the participant.

Questions with a grey background are to be answered by the interviewer or the study centre and should not be addressed directly to the participant.

Questions with a light green background are to be asked only when first morning urine is collected.

Questions with a light red background **only have to be asked if (a) urine sampling is not foreseen** in the survey **or** if (b) blood and urine sampling did not happen at the same time (**> 1 h between sampling of blood and sampling of urine**).

1.1 General questions regarding the sample itself

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
<p>U1. Has the [first morning] urine sample been delivered?</p> <p>B1. Has the blood sample been taken?</p>	<p>These questions all serve to provide background information on if and how the blood or urine sample has been obtained and handled in the participant's home.</p>	<p>To be answered by Interviewer: If this question is answered with no, the questionnaire does not have to be applied. Depending on the individual study design, a reschedule of a sampling date has to be appointed in this case.</p>
<p>U2. Was the urine sample collected in the provided container?</p>	<p>Asking the participant for the last time he or she urinated before providing the urine sample is important as a plausibility check (is the sample really the first morning urine?) and might be useful to explain other unusual characteristics of the sample.</p>	<p>To be answered by Interviewer: the sample should be discarded if another container than the provided one has been used to collect the sample.</p>
<p>U3. Is there a sampling label on the container?</p>		<p>To be answered by Interviewer: Check if there is a visible, readable label on the sample container containing information about date and time the sample was taken. Can be merged with U4 if only one label exists.</p>
<p>U4. Is there a label with the correct participant ID on the container?</p>		<p>To be answered by the interviewer: Check if there is a visible, readable label with the participant ID (cross-check with IDs noted down on questionnaires) on the container. Can be merged with U3 if only one label exists.</p>
<p>U5. When was the [morning] urine sample obtained?</p> <p>B2. When was the blood sample obtained?</p>		<p>To be answered by Interviewer: Check if the date and time has been noted down on the container and write it down in the questionnaire or ask the participant.</p>
<p>U6. Is it really the first urine after waking up?</p>		<p>Only to be asked when first morning urine is collected. If the time of the sampling is not in the hours of the morning, meaning up to a max. 12 pm, ask the participant(s) whether this time is correct and whether it is really the first urine after waking up.</p>
<p>U7. When was your last meal before urine sample collection?</p> <p>B3. When was your last meal before blood sample collection?</p>		<p>Note down the date and time the participant last ate (important: small snacks count as well!) before collecting the sample.</p>

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
U8. When did you last urinate before urine sample collection?		Note down the date and time the participant last urinated before collecting the sample.
U9. According to your information, the last visit to the toilet was at least 4 hours before sampling!		Only to be stated when first morning urine is collected. Check for plausibility by comparing with answer provided under U6.
U10. How was the sample stored at home before collection?		It is important to know if the sample has been cooled or not during the time between sampling and interviewer appointment.
U11. Is the morning urine sample complete? Complete means that all morning urine was collected for the urine sample!		U11 should only be included if the study is foreseen to use containers big enough to collect all morning urine. Only to be asked when first morning urine is collected.

1.2 Residential environment and home exposures

QUESTIONS	JUSTIFICATION	ASSOCIATED SUBSTANCE GROUP(S)	INFORMATION FOR INTERVIEWERS
<p>U12. Have you been outdoors (walking, cycling, etc.) next to a street with constant traffic during the 24 hours prior to sampling?</p> <p>U12a. How long in total have you been outdoors (walking, cycling, etc.) next to a street with constant traffic during the 24 hours prior to sampling?</p>	Traffic is a potential source of PAHs.	PAHs	Please note that constant traffic means cars continuously circulating.
<p>U13. Have you inhaled smoke from the following energy sources inside your home during the 24 hrs prior to sampling?</p>	Combustion processes are a potential source of PAHs.	PAHs	?

1.3 Dietary habits

QUESTIONS	JUSTIFICATION	ASSOCIATED SUBSTANCE GROUP(S)	INFORMATION FOR INTERVIEWERS
<p>U14/B9. Before providing the sample, when did you last eat any food belonging to the following food groups?</p>	<p>For some substance groups, it is important to learn when the last possibility for exposure with this substance group took place, i.a. when the participant last ate a potentially contaminated food item. Food items can be a source of exposure for different and various substances. Food items have been grouped according to the groups found in the basic questionnaire.</p>	<p>Phthalates & substitutes: Fish and seafood, Meat, Dairy products and eggs, Cereals, Fats, Vegetables, Fruit, Hazelnut spread, ice cream, jelly candies, Fast food, Ready meals (in plastic packaging) Bisphenols: Canned food Chromium: Fresh fish, white meat, bread and Cereal products, vegetables and fruit (e.g., basil, black pepper, broccoli, Corn on the cob, garlic, green beans, potatoes), snacks. Cadmium: Fresh fish, crustaceans and shellfish, bread and cereal products, offal, vegetables and fruit (e.g., carrots, fresh tomatoes, leafy vegetables such as lettuce, spinach, onions, potatoes, soybeans, sunflower seeds) and snacks like peanuts PAHs: Smoked food, Grilled food, Fried food, Toasted bread Flame retardants: fish and seafood, meat, dairy products and eggs, fats PFAS (measured in blood): Eggs, Popcorn (microwaved/home-made)</p>	<p>Important: Please keep reminding the participant that this question is directed at the time before sampling. If necessary, give an example like '24 hrs ago in this question is not yesterday around this time now, but yesterday around the time you provided the sample.' If the participant names food items, but not groups kindly ask if they could sort the items into one of the groups.</p>
<p>U15./B10. During the past 24 hrs prior to sampling, did you drink beverages from any of the following materials?</p>	<p>Some materials used for food and drink contact are prepared using 1st priority substances in the process. Drinking from a container that is contaminated</p>	<p>Bisphenols: plastic bottle, can, plastic mug or glass</p>	<p>All beverages are asked for including water, hot drinks, alcoholic drinks, juices, lemonades, etc.</p>

	with a certain substance group can be a source of exposure to this substance group.	Phthalates: Plastic bottle, can, plastic mug or glass, polystyrene, cardboard	This question is just aiming at the material of the container the beverage was in.
U16./B12. Before providing the sample, when did you last drink any beverages belonging to the following list?	For some substance groups, it is important to learn when the last possibility for exposure with this substance group took place, i.e. when the participant last drank a potentially contaminated beverage. Beverages can be a source of exposure for different and various substances.	Chromium: barley coffee, beer, fruit (grape and orange juice), red wine, whole milk. Cadmium: Sakè , vegetable (tomato) juice.	Important: Please keep reminding the participant that this question is directed at the time before sampling. If necessary, give an example like '24 hrs ago is not yesterday around this time now, but yesterday around the time you provided the sample.' If the participant names food items, but not groups kindly ask if they could sort the items into one of the groups. Barley coffee is also known as Caffè d'orzo.
U17. Did you eat fast food in the past 24 hrs prior to sampling? U17a. How was the fast food packed that you ate during the past 24 hrs prior to sampling?	Fast foods are pre-prepared meals that can come into contact with 1 st priority substances during the preparation process and through the packaging.	Phthalates & substitutes Bisphenols	Fast foods processed foods that are easily prepared and served quickly in snack bars and restaurants, typically packed to be 'to-go'. If the participant selects yes, please note that participants can select multiple type of food contact materials, most of them considered as possible sources of prioritized substances. However, other food contact materials such as aluminum or glass are possible.

1.4 Lifestyles

QUESTIONS	JUSTIFICATION	ASSOCIATED SUBSTANCE GROUP(S)	INFORMATION FOR INTERVIEWERS
<p>U18. Have you been exposed to tobacco smoke during the 24 hrs prior to sampling?</p> <p>U18a. How many cigarettes during the 24 hrs prior to sampling?</p> <p>U18b. How long have you been exposed to second hand smoking during the 24 hrs prior to sampling?</p>	<p>Exposure to tobacco smoke by smoking and passive exposure to tobacco smoke is a source of exposure to PAHs and anilines.</p>	<p>PAHs, Anilines & MOCA</p>	<p>The question aims at both active smoking and passive smoking (= exposure to second hand smoke). Passive smoking means that the participant was exposed to tobacco smoke but was not smoking herself/himself. Participants who have smoked are asked U18a. Participants who have been exposed to second hand smoke are asked U18b.</p>
<p>U19. Have you used snuff during the 24 hrs prior to sampling?</p> <p>U19a. How many loadings during the 24 hrs prior to sampling?</p>	<p>Snuffing is a source of PAHs.</p>	<p>PAHs</p>	<p>This refers to a variety of smokeless tobacco products delivered through oral mucosa or nasal cavity.</p>

<p>U20./B13. During the past 48 hrs prior to sampling, when did you last participate in any of the following activities?</p> <p>U20a./B13a. Did you wear personal protection equipment (e.g. a facemask) during one or more of the above-mentioned activities?</p>	<p>Many activities include contact with materials or substances that can include 1st priority substances.</p>	<p>Phthalates & substitutes: Home repairs/maintenance and construction activities, plastic handling Bisphenols: Surface treatment, Cleaning and reparation products, Home repairs/maintenance and construction activities, Plastic handling Chromium: Surface treatment, Cleaning and reparation, Home repairs/maintenance and construction activities, Gardening, Handling metals, Use of dyes and inks, Application of pesticides Cadmium: Surface treatment, Gardening, Handling metals, Use of dyes and inks Anilines & MOCA: Cleaning and reparation, Home repairs/maintenance and construction activities, Use of dyes and inks, Application of pesticides PAHs: Contact with smoke from outdoor open fire PFAS: Surface treatment (specifically surface protection agents for textiles etc.)</p>	<p>It is important that the participant understands this question aims at investigating all activities (e.g. housework, DIY activities, hobbies) that could cause a non-occupational exposure to the substance. It would be advisable for the interviewer to provide examples for each of the activities (e.g. Construction/building or renovating/redecoration activities: exchanging flooring or wallpaper, use of paints, glues and adhesives; Gardening activities: use of pesticides; Wood processing: restoration of wood furniture, cutting and smoothing wood; etc.)</p>
--	--	--	--

U21./B14. When did you last use any of the following personal care products in the past 48 hours prior to sampling?	Personal care products and cosmetics are widely used. Complete information on the use of these products is needed to achieve a proper characterization of the exposure in humans.	Phthalates & substitutes: cosmetics, body care products Anilines & MOCA: Hair products PFAS: Cosmetics and sun cream (sunscreen)	Hair products include for example shampoo, hair spray, perming products, hair dye or bleach. Cosmetics for example include make-up, but also nail polish and nail polish remover. Body care products for example include body lotion, shower gel and deodorant.
U22. Did you take any of the following types of medication during the past 24 hrs prior to sampling?	Coatings of pills and capsules can be a source of exposure for phthalates and substitutes. Anilines could be used as raw materials of various pharmaceuticals and medication could be a source of exposure to anilines. Paracetamol, as a single active drug, is a major metabolite of aniline.	Phthalates & substitutes Anilines & MOCA: paracetamol	Only paracetamol (in any form) as well as medication in pill or capsule shape is relevant here.
U23. During the past 24 hrs prior to sampling, did you undergo one or more of the following medical treatments?	Medical equipment (e.g. plastic tubes used for dialysis) can contain substances of interest.	Phthalates & substitutes Anilines & MOCA	Dialysis is a treatment method for loss of kidney function. This question aims to clarify contact with (e.g. polyurethane) medical devices/plastics.
U24. In the past 24 hrs prior to sampling, did you put things made out of plastic material (e.g. pens, toys) in your mouth to chew on?	Products made out of plastic can often include plasticisers like phthalates and substitutes. Chewing or sucking on these products can be the reason for oral uptake of these substances.	Phthalates & substitutes	-

1.5 Important when children are the target group

QUESTIONS	JUSTIFICATION	ASSOCIATED SUBSTANCE GROUP(S)	INFORMATION FOR INTERVIEWERS
[U25. How long did your child spend on the floor (e.g. playing, crawling) during the 24 hrs prior to sampling?]	Young children, due to their body height or inability to walk upright as well as due to their child-specific behaviour ('mouthing') come in contact with house dust which can be a source of exposure for various substances.	Phthalates & substitutes	This question is only asked when toddlers or young children are participating.

1.6 Important when toddlers or young children (up to 4 years) are the target group

QUESTIONS	JUSTIFICATION	ASSOCIATED SUBSTANCE GROUP(S)	INFORMATION FOR INTERVIEWERS
[U26. Did your child use a pacifier within the last 24 hrs prior to sampling? U26a. How long in total did the child use a pacifier?]	Products made out of plastic can often include plasticisers like phthalates and substitutes. Chewing or sucking on these products can be the reason for oral uptake of these substances.	Phthalates & substitutes	This question is only asked when toddlers or young children are participating.
[U27./B15. Did you use any of the following toddler foods during the 24 hrs prior to sampling?]	Toddler foods can be a source of exposure for Bisphenols.	Bisphenols	This question is only asked when toddlers or young children are participating.

1.7 Any other questions

QUESTIONS	JUSTIFICATION	ASSOCIATED SUBSTANCE GROUP(S)	INFORMATION FOR INTERVIEWERS
U28./B16. Were there any peculiarities with the sample or participant's answers?	This question serves to document anything worth documentation.	-	If you noticed anything in specific (e.g. the sample has been handled a certain way) please note it down here.

1.8 Extra questions included in the questionnaire accompanying the blood sampling

QUESTIONS	JUSTIFICATION	ASSOCIATED SUBSTANCE GROUP(S)	INFORMATION FOR INTERVIEWERS
B4. What total amount was sampled?	-	-	Enter here the gross volume of blood taken in millilitres.
B5. If the gross volume was taken in sub-samples: How many sub-samples were taken?	-	-	Enter here the number of tubes and volume of blood in each tube in millilitres.
B11. When was the last time you ate dishes from communal catering such as from a canteen, dining hall or cafeteria (e.g. at nursery, school or at work/training pace) prior to providing the [morning] urine sample?	Communal catering can be a source of exposure for bisphenols.	Bisphenols	-



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Annex 2.1.5

Concept for the development of non-responder questionnaires in the scope of HBM4EU

WP 7

Task 7.3

D7.3

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Many thanks also to Christine Schulz (UBA) who shared valuable experience from the past and current German Environmental Surveys!

This document has been created for the HBM4EU project. HBM4EU has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733032.

1 Aim of this concept

One of the main goals of the HBM4EU programme is working towards the harmonisation of procedures and tools for HBM across the EU member states, its associated and partnered countries. A step towards this goal is the establishment of a European HBM platform which is foreseen to provide foundation for the design and implementation of HBM studies across Europe.

Survey design and fieldwork preparation, a key part of this HBM platform, include the development of questionnaires.

In order to aid in filling various data gaps across the partner countries, HBM4EU questionnaires are required to comply with different studies easily, e.g. entirely new studies or already existing studies which are extended with some parts to deliver comparable results in the frame of HBM4EU (see also D7.3). To fit within the limits of the HBM4EU programme, it is most likely that studies of the cross-sectional type are to be conducted or aligned. Recruitment procedures need to be adaptable to different age groups or certain target groups (occupational area, groups with high risk) and are further required to be equipped to manage the challenges of achieving representativeness. Non-responder questionnaires are a perfect instrument to collect more information on randomly selected potential participants who refrain from taking part which affects the representativeness of the study.

In this document, a concept for a non-responder questionnaire to accompany studies performed under HBM4EU is presented. Assessing non-response and addressing its reasons and effects is important when the study is aiming for a representative coverage of the population.

This concept for the development of non-responder questionnaires in the scope of HBM4EU is primarily based on experiences collected in the German Environmental Surveys (GerES), cross-sectional population representative studies. The concept addresses the reasons for and effects of non-response and aims at covering adjustment for losses and weighting and delivers a proposal for aspects which should be considered when creating a non-responder questionnaire. Finally, a proposal for a general non-response questionnaire to accompany the HBM4EU basic questionnaire on the 1st priority substances is provided.

2 Non-response

When interpreting data from a population-based study, it is important to know if there was a systematic difference of characteristics between those who took part in the study and those who declined participation in the study (O'Neill, Marsden et al. 1995).

Non-response is defined as 'failure to obtain a measurement on one or more study variables for one or more elements selected for the survey' (OECD 2002). On data, it can have two main effects. It can introduce bias (if non-respondents systematically differ from the respondents) and, due to the sample size observed being reduced from the originally planned sample size in case of non-response, it contributes to an increase in total variance of estimates (Statistics Canada 2009), i.e. increases inaccuracy of the estimates.

Low response rates are unfortunately typical for observational exposure studies (Callahan, Clickner et al. 1995). It is therefore paramount to adjust for those individuals of the gross sample who will reduce the originally planned sample size, either because they can be considered as quality-neutral loss or because they declined participation even though they were eligible for response (herein referred to as 'Eligible Respondents', see Figure 1) (Schnell 1997). Subsequently, analysis for bias needs to be performed.

The following Chapter 3.1 elaborates on how and why the gross sample needs to be adjusted for potential losses that are considered quality-neutral. This is reflected in the first level of Figure 1, in the split of the gross sample in quality-neutral losses (QNL) and Eligible Respondents. Chapter 3.1.1. provides details on the measurement of these quality-neutral losses which is tightly interconnected with the measurement of other (systematic) losses. These losses can happen at the second level of Figure 1, indicated by the split between those Eligible Respondents that accept and those that decline participation. The adjustment process for this is briefly outlined in Chapter 3.2 on weighting.

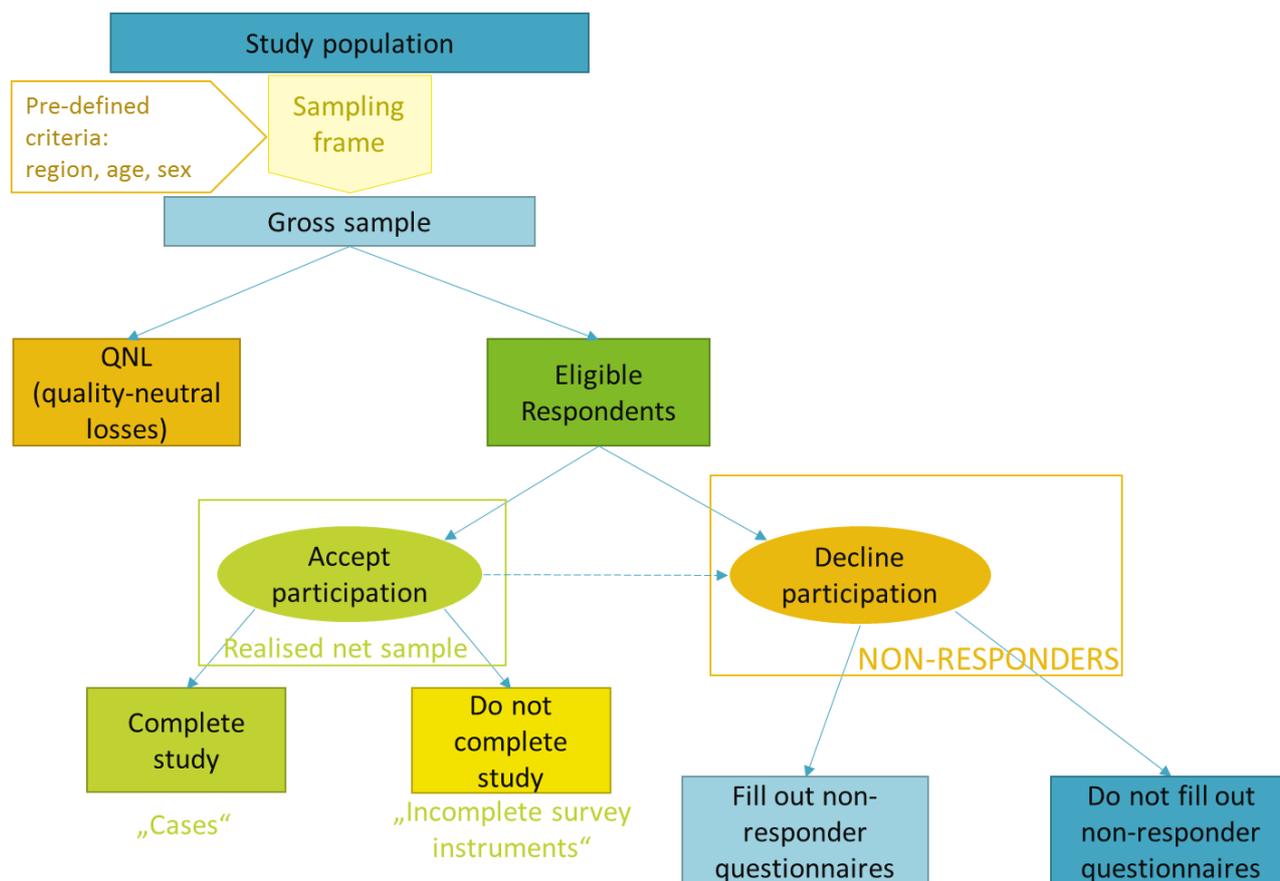


Figure 1: Schematic breakdown of the sample according to participant reaction

2.1 Adjusting the gross sample by QNL

In order to achieve a number of individuals representative for the target population's distribution of criteria (e.g. region, age, sex), a gross sample is drawn from the target population following the sampling frame, e.g. a population register or a list of schools, covering these criteria. This sample is also often referred to as original sample. More examples for sampling frames are elaborated on in the Concept for a Study Protocol (Annex 1 to Deliverable 7.3).

Examples in the following are provided mainly for situations in which population registers are used to draw the gross sample.

Every gross sample drawn is likely to have quality-neutral losses (QNL). According to the former Centre for Surveys, Methods and Analyses (ZUMA) in Germany, QNL are defined as losses of address drawn via the sampling frame that are unavailable for the study, but not due to a third person involved (e.g. the interviewer or the target person) (Porst 1996). Reasons for this can, for

example, be the specified street or house number cannot be found, the flat is uninhabited, unused addresses, or no person in the household belongs to the intended target group (VDI-3883 2015). The latter criterion can take the shape of several new criteria such as target person is older than a certain age or the communication with participant is impossible (speech impediments or language barrier) (Kamtsiuris, Lange et al. 2007).

In order to adjust the sample for these losses, the QNL are deducted from the gross sample to define those individuals that count as Eligible Respondents (see Figure 1). Like all losses, if not adjusted for, QNL can contribute to an increase in total variance of estimates due to the difference in observed and originally sought sample size (Statistics Canada 2009). It is important to define which losses are classified as ‘quality-neutral losses’ at the beginning of a survey (see Table 1).

2.1.1 Measuring QNL

There can be many different reasons why an individual that has been drawn as part of the gross sample does not end up as part of the net sample.

During the recruitment process, it is essential that the result of each contact to an address drawn for the gross sample is documented (DGEpi 2008). Codes for each possible result like ‘agreement to participate received’, or ‘no information about reasons for non-participation’ and also reasons for non-participation should be provided. It is recommended to compile a list with all such result codes in advance and define clearly which will be considered as quality-neutral loss and which will not (examples see Table 1 or table 5.1 of the report on the German national consumption survey II (MRI&BMEL 2008) included in the references). Every address or individual, depending on the sampling scheme, drawn for the gross sample should receive one of these codes. In order to make the result codes (usually numerical with a brief title) easily understandable and applicable by the study staff, they should be connected to a description at when this code has to be selected. An example for this would be if the participant expresses doubts about data protection measures in some form (despite being provided with the data protection statement) and does not wish to participate because of this, the code for ‘doubts about data protection measures’ has to be selected.

As due to ethical reasons individuals cannot be contacted again as soon as they finally decline participation, it is recommended to document these reasons already during the individual recruitment procedure. If the individual agrees, this can be combined with the application of a non-responder questionnaire.

In Table 1, some examples for result codes including possible reasons for non-participation and their typical classification (as QNL or not) are shown. They are selected for a sample that has been drawn from an address-based system, such as a population register. The list of codes has to be put together or at least adjusted for each study individually, taking specifically into account the sampling frame. Point 04 ‘Flat uninhabited’ for example would not apply if a sample is selected on individual basis.

Table 1: Examples for result codes including reasons for non-participation and definitions of QNL for an address-based sample

Number	Result code	Quality-neutral loss?
02	Agreement to participate received	-
03	No information about reasons for non-participation (e.g. no successful contact)	No
04	Flat uninhabited	Yes

05	Doubts about data protection measures	No
06	Acute or chronic illness	No
07	Not interested, not convinced by purpose of the study	No
08	Death of individual	Yes
09	Long-term absence during entire study duration	Yes
10	Moved away from the study area	Yes

2.1.2 Other losses

Examples for (systematic) losses that are not quality-neutral could be typically the refusal of participation, the termination of an interview or the inaccessibility of the target person after a set amount of contact attempts (VDI-3883 2015). Table 1 also shows three examples of losses that are typically not considered quality-neutral: illness, doubts regarding data protection and lack of interest. There are of course many more reasons which should all be considered, listed, coded and described in detail.

2.2 Weighting

‘A typical survey objective is to estimate descriptive population parameters, as well as analytical parameters, on the basis of a sample selected from a population of interest.’ (Statistics Canada 2009).

In order to estimate those parameters correctly, the sample needs to be representative of the study population.

Losses from this (gross) sample, quality-neutral or not, therefore need to be adjusted for. While QNL can be simply deducted from the gross sample (therefore providing the adjusted gross sample or Eligible Respondents as described above), other, potentially systematic, losses need to be addressed more specifically.

In order to do so, the total participant numbers (the realised net sample, see Figure 1) can be split up in groups according to the criteria comprising the sampling frame (e.g. age groups, gender groups, region size groups). The distribution within these groups of the net sample can be statistically adjusted (weighted) to better represent the distribution present in the original gross sample drawn.

An example would be the distribution in the group ‚sex‘: A gross sample for a study originally included, e.g. 200 women and 200 men (leading to a distribution of 50% women and 50% men in the total gross sample of 400). But only 100 women and 150 men participate (comprise the net sample), i.e. leading to a distribution of 40% women and 60% men, instead of 50% each. In this case, the data collected from the women would need to be weighted in more than that of the men in order to represent the original distribution of 50/50 across the original gross sample.

In addition to weighting, there are methods such as multiple imputation, Bayesian data augmentation, expectation-maximization and others (overview in Tolonen (Ed.) 2016) that can be used to estimate potential effects of non-participation.

2.3 Non-responder questionnaire

The non-responder questionnaire lastly is a tool to assess bias in the study population according to certain factors (e.g. their exposure levels). It is a short questionnaire created to document key criteria of the Eligible Respondents that have declined participation (see Figure 1). This serves in order to be able to assess possible (systematic) differences in these key criteria between those that participate and those that decline participation. Using information from the non-response questionnaire, adjustment for non-response bias through statistical modelling is aimed at.

A non-response questionnaire should be designed to contribute to the determination of defined characteristics that influence exposure.

3 Recommendations for the development of non-responder questionnaires

A questionnaire specifically addressed at individuals that have declined participation needs to be designed to take into account and carefully weigh the individual decision for non-participation against the scientific interest in information about exactly those individuals.

Therefore and based on expertise gathered in five rounds of conducting the German Environmental Survey (GerES), non-responder questionnaires should be kept as short and compact as possible to reduce participant burden to an absolute minimum. Wherever possible, questions should be asked in a way that makes it possible to answer with 'Yes', 'No' or 'Don't Know'. 'Refusal' of a single question should also be possible to note.

It is of interest to be able to compare the group of participants that declined participation in the study but who have provided answers to the non-responder questionnaire to those participants that have accepted participation and completed the study. Therefore, questions in a non-responder questionnaire need to be identical or at least highly comparable to those asked in the main (= basic) questionnaire.

As for all questionnaires, it is highly recommended to determine if questions and items in the non-responder questionnaire are well understood and it is generally possible to provide an answer. This can be done, for example, in a pre-test on a small sub-sample of test participants.

The questions comprising a non-responder questionnaire can be split up into two groups, the essential group that should always be considered for inclusion, especially when other sampling frames than national population registers are used, and the group that could be skipped if the participant refuses to spend more time answering the non-responder questionnaire.

In the essential part of the questionnaire, the criteria which led to the original selection of the gross sample need to be included (e.g. age, region, sex) if they are not already known due to the sampling frame (e.g. address or phone number of participant can provide enough information of the region). Questions covering the original sampling criteria are essential, especially when other sampling frames than national population registers are used as these criteria can ensure correct classification of the participant within the gross sample.

The remaining timeframe for questions can then be covered with questions aiming to determine potential exposure of the non-participant to substances or groups thereof of interest. As mentioned above, these questions should be comparable to those in the basic questionnaire and should be reduced to those pathways that highly influence concentration of the substance group(s) of interest or their metabolites the most.

In brief:

- ▶ As short and compact as possible (2-5 minutes maximum) to reduce participant burden to an absolute minimum, if possible: only yes/no/don't know
- ▶ Questions need to be identical or at least highly comparable to those asked in the main questionnaire of the study (e.g. basic questionnaire)
- ▶ Essential questions (especially when other sampling frames than population registers are used): cover criteria which led to the original selection of the gross sample (e.g. age, region, sex)
- ▶ Other questions: cover specific exposure routes, often main path of exposure for the substance (group) of interest

4 Non-responder questionnaire in the scope of HBM4EU

Below you find exemplary questions that could be used to compile a HBM4EU non-responder questionnaire.

Each question is briefly introduced and the rationale behind its selection is explained to give an impression of the reasoning behind the selection of questions for a non-responder questionnaire. Other questions fulfilling the same function could be used as well.

At the same time it has to be noted that these exemplary questions might have to be adjusted if someone provides answers for the participant (e.g. a parent for a child). Also, the reasons for participation (see below 'For what reason did you decline participation in the study?') need to be adjusted according to the study design.

For each study the decision has to be made separately which questions of the basic questionnaire should be transferred to the non-responder questionnaire.

Reply cards can be used in studies to ask for the willingness of the potential participant to participate in the study. These cards can be specifically designed for non-participants and include questions to determine at least a few characteristics about the declining participant. An example for such a reply card can be found in D7.4 '1st material for communication to participants, including informed consent'.

4.1 Questions considered essential for a non-responder questionnaire

What questions are considered essential can vary depending on the intentions of a study. This concept assumes that representativeness is aimed at in the study it is applied in.

Following, the three questions which comprise the essential part of the questionnaire are depicted as examples. As mentioned already in Section 4, sex and age are criteria which are foreseen to be used for the original selection of the gross sample. The criterion 'region' is assumed to already be known due to the possibility of contacting the participant (e.g. address or phone number of participant used to reach him or her with this questionnaire can provide enough information of the region). To save time it is therefore not included as a question.

It could be useful to consider adjusting the basic questionnaire to ask the questions first that have been identified as essential in the non-responder questionnaires. That way, participants that cancel the interview are more likely to have already provided the most important data.

A good introductory question for the non-responder questionnaire is asking for the reason why the participant has declined participation in the study in the first place.

For what reason did you decline participation in the study?

Interviewer: Only **main reason** should be selected.

- Absence during the time of the survey
- Acutely or chronically ill
- No time
- Not interested or not convinced by purpose of the survey
- Doubts about data protection measures
- Too much effort (survey takes too long)
- Generally decline participation in surveys
- Others, specify: _____

Don't know Refused

Rationale behind the question: As mentioned in Section 3.1.2, the question above serves to determine the reason why potential participants decline participation in the study and helps adjusting the sample for loss.

For example, in case of a home visit by the interviewer, one of the reasons for non-participation could be that the potential participant declines participation due to the home visit. This should be adequately reflected in the possible choices of reasons.

What is your sex?

Interviewer:

- Male
- Female

Don't know Refused

Rationale behind the question: If sex is one of the selection criteria for the gross sample, it is considered an essential question and should be asked early on in the questionnaire. Sex is also relevant when determining exposure to substances (e.g. phthalates).

What is your birth date?

Month

Year

Don't know Refused

Rationale behind the question: If age is one of the selection criteria for the gross sample, it is considered an essential question and should be asked early on in the questionnaire. Age is also

potentially relevant when determining exposure to certain substances or substance groups (e.g. phthalates, BPA, PFAS, FR, Cd, Cr, PAHs, anilines).

4.2 Optional or substance-related questions for a non-responder questionnaire

The questions below are exemplary and need to be carefully selected for each study individually, depending on the questions (and their wording) used in the study's basic questionnaire and the substances and substance groups of interest. As elaborated in Section 4, the overall number of questions in a non-responder questionnaire should be kept as small as possible. Due to the fact that in HBM4EU several substances and substance groups have to be covered in all questionnaires, the following selection of questions is quite extensive.

Which fuels or sources of energy are used in your home for heating?

Interviewer: Only **main reason** should be selected.

- Charcoal/Coal
- Wood
- Wood pellets
- Others

Don't know Refused

Rationale behind the question: As they could potentially release smoke indoors, (Char)coal and wood (pellets) used as fuels can be a source of exposure with PAHs. This question serves to briefly address possible PAH exposure in the home and is easy and quick to answer (unlike a more difficult question directed at the traffic outside for which the type of street would have to be determined which could lead to confusion).

In the last 4 weeks, did you consume fast food (please consider also beverages)?

Interviewer: Fast food is commercially prepared, processed food that is ready to eat as a quick meal or for takeaway. Consider also beverages.

- Yes
- No

Refused

Rationale behind the question: Fast food is often packaged with food contact materials possibly containing phthalates, BPA, PFAS and other priority substances. This question requires the additional information of what is meant by 'fast food', but is highly relevant as it is an important exposure pathway for the above mentioned substance groups and therefore included here.

What is the main source of your drinking water?

Interviewer: Only **main reason** should be selected.

- Public network
- Private well

<input type="checkbox"/>	Bottled water (plastic)		
<input type="checkbox"/>	Bottled water (glass)		
<input type="checkbox"/>	Others		
		Don't know	<input type="checkbox"/> Refused <input type="checkbox"/>

Rationale behind the question: Depending on the source, drinking water can be a source of phthalate and BPA exposure. The origin of drinking water could be also associated with the exposure to PFAS. This question is quick to answer as it requires only one option to be chosen and is relevant for several substance groups.

In relation to smoking habits, which of the following options best describes your situation?

Interviewer: Only **one option** should be selected. Smoking refers to cigarettes, cigars, pipes, and electronic cigarettes.

<input type="checkbox"/>	I have never smoked		
<input type="checkbox"/>	I was a smoker but I gave up smoking		
<input type="checkbox"/>	I currently smoke occasionally		
<input type="checkbox"/>	I currently smoke daily		
		Don't know	<input type="checkbox"/> Refused <input type="checkbox"/>

Rationale behind the question: Smoking is a known source of exposure for substance groups such as PAHs, Cd, Cr, BPA and anilines. This question requires the additional information of which type of smoking is meant here, but is highly relevant for several substance groups and therefore included here.

During the past 48 hrs, did you use any products belonging in one of the following categories?

Interviewer: To help the participant '48 hrs ago is the day before yesterday around this time' can be said. Please note that several options can be selected.

	Used during past 48 hours	Not used during past 48 hours	Don't know
Hair products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Body care products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cosmetics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			Refused <input type="checkbox"/>

Rationale behind the question: Contact with hair (treatment) products, like dyes, can be a path of exposure for anilines. Humans can also be exposed to phthalates and substitutes as well as BPA when using body care products like body lotion, deodorant, creams and cosmetic products. Specific types of cosmetics, like water-resistant make-up and nail polish could be associated with exposure to PFAS.

What materials is most of the floor covering in your home made of?

Interviewer: Only **main materials** should be selected. Most refers to more than half of the entire floor in all rooms.

- Wood-parquet
- Wooden planks
- Laminate
- PVC
- Linoleum
- Tiles
- Synthetic fibre
- Natural fibre
- Natural or synthetic fibre with plastic backing
- Others

Don't know Refused

Rationale behind the question: The floor covering is considered an important source of indoor exposure to certain compounds, especially phthalates, BPA, PFASs and FR. This question requires the additional information of what 'most of the floor covering' means, but is highly relevant for several substance groups and therefore included here.

4.2.1 Questions potentially causing discomfort for the participant

Questions considered to touch upon private matters such as employment status and weight are purposefully asked at the end of the questionnaire to avoid early cancellation of the interview. Examples of such questions are provided in the following.

How tall are you without shoes (in cm)?

cm

Don't know Refused

How much do you weigh without clothes and shoes (in kg)?

kg

Don't know Refused

Rationale behind the questions: Body weight has been shown to correlate with exposure to certain substances such as phthalates. Height is asked for determination of the Body-Mass-Index. This question is positioned at the end of the questionnaire as it is potentially unpleasant to answer for the participant.

What is the highest level of education you attained?

Interviewer: Only **one option** should be selected.

- No formal education or below primary education (ISCED 0)
- Primary education (ISCED 1)
- Lower secondary education, or second stage of basic education (ISCED 2)
- Upper secondary education (ISCED 3)
- Post-secondary non-tertiary education (ISCED 4)
- Short-cycle tertiary education (ISCED 5)
- Bachelor's or equivalent level (ISCED 6)
- Master's or equivalent level (ISCED 7)
- Doctoral or equivalent level (ISCED 8)

Don't know Refused

What is your current main labour status?

Interviewer: Only **one option** should be selected.

- Employee working full-time
- Employee working part-time
- Self-employed working full-time (including family worker)
- Self-employed working part-time (including family worker)
- Unemployed
- Pupil, student, further training, unpaid work experience
- In retirement or in early retirement or has given up business
- Permanently disabled or/and unfit to work
- In compulsory military community or service
- Fulfilling domestic tasks and care responsibilities
- Other inactive person
- Other status, specify: _____

Don't know Refused

Rationale behind the questions: The questions are used to achieve an impression of the participant's socio-economic situation, which could be used to develop an indicator of occupational social class. SES can be a determinant of exposure to phthalates, PFASs, BPA, FR, Cd, Cr, PAHs and anilines (1st priority substances). This question is positioned at the end of the questionnaire as it is potentially unpleasant to answer for the participant.

4.2.2 Questions directed exclusively at a sub-group of participants

The following question should be addressed at women only:

Are you currently breast-feeding or have breastfed?

Interviewer: Only ask this question to women.

Yes

No

Refused

Rationale behind the questions: Breast feeding history could affect the concentrations of certain compounds in humans (e.g. PFASs, FR). This question is only directed at female participants.

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Annex 2.1.6

Satisfaction Questionnaire

WP 7

Task 7.3

D7.3

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This document has been created for the HBM4EU project. HBM4EU has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733032.

1 Introduction and aims

The satisfaction questionnaire aims to provide information on the entire process of HBM4EU project according to the satisfaction level of the participants, in order to find out potential limitations, as well as to improve the development of this and similar biomonitoring studies.

Since it is a brief and easy to complete questionnaire, a link will be given to the participants after the interview to invite them to fill out this questionnaire online.

		1-Completely disagree					10- Completely agree					
Please, mark in the chosen box your satisfaction level regarding the following items:		1	2	3	4	5	6	7	8	9	10	N/A
11.	You felt comfortable to provide the urine sample											
12.	You felt comfortable to provide the blood sample											
Accesses and facilities												
13.	In general, you found easy to reach and access to the meeting point (e.g. clinic, hospital) for the collection of biological samples (e.g. satisfactory transportation (public/private), adapted accesses, easily identified area for the study etc.)	<input type="checkbox"/>										

14. How do you consider the time you spent on this study?

Insufficient Appropriate Long Excessive Don't know

15. Do you perceive that the results derived from this study will lead to improvements in Public Health?

Yes, absolutely Yes, partially No Don't know

16. Would you again take part in a similar study?

No Yes Yes, if some improvements are included (please, specify in question 18) Don't know

17. Would you recommend your family members or friends to participate in this study?

No Yes Yes, if some improvements are included (please, specify in question 18) Don't know

18. Is there anything we could have done better?

19. Overall, rate (1-low, 10-high) your satisfaction level after your participation in this study

1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>									

20. What else would you like to tell us about this study?

THANK YOU VERY MUCH FOR YOUR TIME



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Annex 2.2

Standard Operating Procedures (SOPs)

WP7

Task 7.2

D 7.3



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Annex 2.2.1

SOP 1:

Selection of Participants and Recruitment

WP 7

Task 7.2

D 7.3

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Authors and Acknowledgements

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This document is based on and interconnected with the work done for Deliverable 7.3 and its Annex 1, the Concept for a Study Protocol. We would like to thank all authors mentioned in those documents for their input.

This document has been created for the HBM4EU project. HBM4EU has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733032.

1 Introduction

This guideline is intended to be used in the framework of HBM4EU. HBM4EU aims at establishing a European human biomonitoring platform and filling knowledge gaps in representative exposure data. HBM4EU supports the countries with several documents heading for a harmonisation of study conduct to facilitate generating European reference values. This SOP, together with other documents, is part of the Deliverable 7.3 on study design focussing on recruitment, fieldwork and sampling. Deliverables focussing on other parts of study conduct like ethics, analytics and data management provided by other work packages complement D7.3 for a proper study conduct in the frame of HBM4EU.

Presented here is a guideline or template for a SOP on Selection of Participants and recruitment which will have to be elaborated in each country describing the actual situation and planning in the country.

This template has been created with the premise in mind that every participating country is obliged to try best as possible to follow the HBM4EU documents to achieve comparable data in a (as much as possible) harmonised way. Deliverable 7.3 and its Study Protocol provide additional input on the selected items described below.

2 Study design and participants

This part provides an overview of the general study design and the plans for the participants to be involved. It serves to introduce and explain what is planned to be done in short, precise paragraphs. Below, the topics necessary to be addressed and to be filled with content are listed in bullet point form.

Depending on target population and sampling frame, the methods best suited for obtaining a representative sample can vary.

Describe here:

- ▶ The target population (age, gender): The sampling domains for which at least specified reliability is desired in Europe are gender and age groups. The seven age groups that are targeted within the HBM4EU surveys are: 0-2y, 3-5y, 6-11y, 12-19y, 20-39y, 40-59y, 60-79y.
- ▶ The sampling frame derived from the target population according to the Concept for a Study Protocol (Deliverable 7.3 Annex 1): The way of recruiting the participants (via schools, work, registries) is not prescribed within HBM4EU. However, a good sampling frame model for selection of individuals is the stratified clustered multi-stage design. Using this design, geographical areas (stratification) are selected within a country. Within each of the geographical areas, primary sampling units (PSU: schools, work registries, general practitioners) are selected randomly, however that can be done in a way that there is an increased selection chance proportional to the number of individuals in these PSU. Furthermore, individuals are selected randomly within the PSU.
- ▶ The number of participants required for a (representative) sample size. Keep in mind to refer to the selection of sampling locations here (see Chapter 4): In each participating country, and for each of the selected age groups, 150 male and 150 female participants recruited from the general population (i.e. non-hospitalized individuals) are included. The sample size was chosen to ensure also inclusion of participants from different socio-economic strata and from different community sizes (urban, suburban, rural). To include different socio-economic classes, education level can be used as a proxy (International Standard Classification of Education (ISCED), which includes 9 levels of education (ISCED 2011, see task 7.2 report). The sample size is indicative and may need further adjustment for the specific chemical group because of expected population variability of the biomarker.
- ▶ What measures are taken to deal with unknown response rates (e.g. assumption of response rate and calculation of extra samples to be taken to make up for this): One must anticipate a response rate of around 30%, meaning that the sample frame must have a size which is at least 3 times as large as the targeted sample size needed.
- ▶ Consider a backup solution in case your primary sampling frame is not applicable in a country (e.g. switch from register to school approach)

3 Selection of sampling locations

Description of number and kind (densely, intermediate and thinly populated areas) of sampling locations being selected for the study.

In case one wants to obtain a representative sample in each country, different approaches could be followed depending on the size of the country and the previous experience in national HBM studies. Within a country, sampling could be done in national geographical entities (e.g. provinces, communities, municipalities) with selection probability of these entities proportional to population size. Another approach could be random selection from population registers. Within HBM4EU no prescriptions are set.

After selection of the participants, they will be categorized into three degrees of urbanisation (DEGURBA) http://ec.europa.eu/regional_policy/sources/docgener/work/2014_01_new_urban.pdf). Within this classification system, three types of areas have been identified: densely, intermediate and thinly populated areas. They are defined using a criterion of geographical contiguity in combination with a minimum population threshold based on population grid square cells of 1 km². Based on these grid cells, three urbanization types are defined:

Densely populated area (**cities**): at least 50% living in high-density clusters (alternative name: urban centre);

Intermediate density area (**towns and suburbs**): less than 50% of the population living in rural grid cells, and less than 50 % living in a high-density cluster;

Thinly populated area (**rural area**): more than 50% of the population living in rural grid cells.

With: rural grid cells = grid cells outside urban clusters; urban clusters = clusters of contiguous grid cells of 1 km² with a density of at least 300 inhabitants per km² and a minimum population of 5000; high-density cluster = contiguous grid cells of 1 km² with a density of at least 1500 inhabitants per km² and a minimum population of 50000.

4 Selection of participants and their recruitment

Inclusion and exclusion criteria need to be elaborated and translated into a practical approach. Exclusion criteria, for example, can be related to age, sex, duration of living at the sampling location (e.g. less than 5 years), being in hospital, being homeless, suffering from special diseases, etc.

In brief for HBM4EU: inhabitants from 'densely', 'intermediate' and 'thinly populated' areas are accepted (see Chapter 4). Hot spot areas, with known historical/actual environmental contamination need to be excluded. No further inclusion and exclusion criteria are set. However, following minimal information needs to be collected (in the questionnaire), to have an indication of the population included:

- ▶ Life style: information on smoking and alcohol/drugs use, diet, housing conditions, hobbies and occupational exposure
- ▶ Socio-economic status needs to be documented (using ISCED education levels)
- ▶ Residential history: number of years living in the country
- ▶ Geographical coverage: densely, intermediate and thinly populated areas
- ▶ Sampling time period needs to be reported (no seasonal restrictions are set).

Correct selection of participants with regard to their age is essential. Depending on sampling frame, a selection using age on a key date is not feasible or too difficult (e.g. in schools). It is therefore recommended to use the year of birth as selection criterion.

Just for an overview some popular methods to select participants of different age groups are presented in the following as options depending on the target population. Table 1 provides an overview on the sampling frames feasible for a specific target population, the partner to contact and the recruitment methods to use.

Table 1: Overview on sampling frames, specific target population, contact partner and recruitment methods

Target population (results will be extrapolated for...)	Sampling frame (to select from the list of...)	Contact partner for participant recruitment (providers of participant addresses)	Recruitment methods (individuals are contacted through...)
General population (or separated according to gender/age)	Population register (country, regional)	Registration offices	1. letter 2. letter, email, text message, telephone, internet, personal visit
	Telephone directory (if a valuable source)	Telephone lists (Internet, organisations)	1. telephone 2. See above
Vulnerable population (pregnant, newborns, seniors etc.)	Patient files	GP, Paediatrician, Gynaecologist, Midwife, Hospital/Clinic, Health Centre, Maternity hospital	1. letter, email, telephone, personal visit, information event, 2. See general pop.
Children, adolescents (different age groups)	Kindergartens, kindergarten groups /day care centres, day care centre groups	Kindergarten / daycare centre	1. letter to principal, letter to parents, personal visit, information event for parents 2. See general pop.
	Schools, school classes/Vocational schools, vocational school classes	School/ Vocational school	
Specific occupational population	Employment records, branch organisations	workplace	1. letter to employer, letter to employee, information event 2. See general pop-

The first contact is mainly to the organisation providing the address of the participant. For this purpose, a written document is recommended. The second contact is directed to the participant itself, which is preferable also done by letter but telephone or direct face-to-face information are sometimes possible, too.

The country specific SOP should describe here in detail how the participants will be selected.

Examples for some commonly used sampling frames are given in the following.

4.1 Population register

When choosing e.g. regions or towns as sampling locations, a population register, be it regional or country-wide, can be immensely helpful to allow for a random sampling at the location(s). Population registers usually can provide addresses of individuals, separated by age and/or gender. Therefore, population registers as a method to select participants can be used for adults and mostly for children as well.

They can usually be accessed through registration offices contacted by an official letter. In this letter, the population register is asked to select a set amount of individuals (including a surplus to deal with a minimum assumed response rate of 30%) according to strict procedures elaborated to them.

The letter also includes inclusion and exclusion criteria and an information leaflet on the study.

The random selection of subjects via population registries, stratified by age group and sex is shown in Table 2.

Table 2: Procedure for random selection of 35 subjects via population registries

	Procedure	Note
1	Definition of age groups	Exact definition of age groups according to year of birth (year x - x)
2	List for each age group	Creation of a random list of all subjects of the age group and placement of an at least 8-digit random number to each child
3	Sorting each list	Sort the numbers in ascending order according to the digit number
4	Selection of subjects	Selection of the first 35 subjects in the list per age group
5	List of subjects selected	First name/s Last name Street Street number Postal code Date of birth Sex Nationality Random number Legal representative

If the described procedure is not possible to conduct for the specific registration office or fees taken by the register are unreasonable high, the population registry contact person should be asked to send the list of addresses of all people included in the age group to the study office. The study office will then take care of the randomization according to the procedure described in Table 2.

In case the number of participants in the target group is not sufficient, another population registry of a similar neighbour district has to be contacted, the lists of target groups have to be combined and the procedure described above has to be conducted with that list.

In order to minimize quality-neutral drop outs (e.g. potential participants move away or are hospitalized) the selection should take place close to the start of the actual fieldwork.

The result of this selection process should be to have a list of a set amount (including a surplus to deal with unknown response rates) of potential participants in the chosen age group, stratified by sex.

4.2 Schools (or kindergartens)

If school children have been chosen as the target population, schools are a viable option for participant recruitment. In case population registers are not feasible, schools or the respective school authority can be contacted to request recruitment of pupils. Areas for schools that fit into the sampling location scheme (e.g. 'densely' or 'intermediate') should be selected. It is essential that this selection does not favour specific socio-economic (SES) backgrounds (e.g. different school types like private and governmental schools) as this could lead to social bias which should be avoided. The population should ideally be mixed with regard to socio-economic structure in the chosen areas.

A first step is to settle which institutions are required to give permission before pupils can be contacted. Such institutions could be a ministry or agency, a superintendent of the district or others.

Once the responsible authority is contacted, they can be asked to help create a list of all schools in the selected areas.

Sufficient schools (depending on the number of intended participants) are selected at random. Preferable are those schools that are attended by pupils with different socio-economic background.

When a school has been selected according to these criteria, the principal has to be asked for his or her permission and to support the study and the selection of the classes.

As the principal is in direct contact with the teachers who in turn are in direct contact with potential participants, it is of the essence from here on out to explain the survey and garner interest in it with the involved persons. After consultation of the principal, it is therefore helpful to hold a meeting with the teachers of the eligible classes and representatives of the survey office.

The survey should be introduced to the teachers and the tasks of pupils (and their parents) addressed in detail. Information leaflets shall be handed out for distribution.

Following this meeting, the teachers will soon after explain the survey in class and hand out the information material to the pupils. The teacher has to be instructed if all pupils of the class shall get an invitation or only those born in a selected year. The information material can already include reply cards to be returned within the next two to three days, or an information evening for the parents can be arranged to hand over the reply cards. For motivation, the teachers should be informed that, regardless of their participation, every pupil who brings back the reply card is foreseen to receive a small incentive (e.g. pen, keychain, etc.) from the teacher who collects all reply cards (hidden in envelopes).

The filled out reply cards are then either sent collectively to the survey office by the teacher, or the field staff will pick them up (e.g. directly at the information evening).

An alternative route to select participants from schools requires specific prerequisites in the country. If it is possible to obtain from the school secretariat the list of addresses of the pupils in the selected school(s), the information material and reply cards can be sent directly to the parents of the eligible children. This avoids relying on the support of the school principal and teachers for study participation.

In any way, the result of the selection should be a plethora of positive reply cards collected in the school(s). The next step is then to contact the families to fix an appointment for the involvement in the study with e.g. a home visit and answering questionnaires and providing samples.

4.3 Maternity hospitals

If vulnerable group(s) such as pregnant women or women with a newborn child are to be selected, it is possible to do so via maternity care clinics. Maternity care clinics are generally selected from the list available in a country. As a starting point, the responsible of the selected maternity hospital is contacted via phone. More information on the study is sent after via a letter addressed to the maternity authority, the gynaecologists and the head of the midwives. The maternity authorities will need to discuss participation in their board meeting, and an additional local ethical approval may be needed. Sometimes maternities ask the HBM fieldwork coordinator to introduce the study in front of the maternity board or local maternity ethical committee.

At least, the HBM fieldwork coordinator will visit the maternity care clinic to practically explain the study sampling protocol, sampling materials, and informed consent for study participation to the maternity care clinic personal in charge of the sample collection and recruitment. Within the maternity, the tasks on recruitment are divided, as it suits them best. As principal practical local contact point functions mostly the head midwife or a selected responsible midwife of the hospital.

They need to be very well informed about all sampling details, sample storage conditions, and the study informed consent, so that they are able to further instruct the other midwives. It is of importance that all midwives are familiar with the protocols and sampling procedures, as deliveries happen during different work shifts. Alternatively, for practical reasons, the clinic may organize themselves, so that, only some part of the days (i.e. by part of the midwives), samples are collected.

The women will be asked for participation the day of delivery, upon arrival in the clinic, by the midwife on duty at that moment. She/he collects the signed informed consents and (e.g. cord blood) samples. The samples may be potentially immediately further processed by the midwife or sent internally to the internal maternity clinical lab. In the latter case, the field workers need to give clear instructions, possibly training, and written protocols to the lab personnel.

Within the first days after delivery, further contact with the mothers (that have given their written informed consent) is taken up by the fieldworkers of the study. They visit the mothers within the maternity, or alternatively (in case the mother has returned home), the fieldworker will contact her via phone or email, to collect the filled out questionnaire, and provide any further information needed.



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Annex 2.2.2

SOP 2:

Quality Assurance for Recruitment and Fieldwork

WP 7

Task 7.2

D 7.3

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Authors and Acknowledgements

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This document has been developed by Ulrike Fiddicke and Kim Pack from the German Environment Agency (UBA).

This document is based on and interconnected with the work done for Deliverable 7.3 and its Annex 1, the Concept for a Study Protocol. We would like to thank all authors mentioned in those documents for their input.

This document has been created for the HBM4EU project. HBM4EU has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733032.

1 Introduction

This guideline is intended to be used in the framework of the Human Biomonitoring Initiative (HBM4EU). HBM4EU has the aim to establish a European human biomonitoring platform and to fill knowledge gaps in representative exposure data. HBM4EU supports the countries with several documents heading for a harmonisation of study conduct to facilitate generating European reference values. This SOP, together with other documents, is part of the Deliverable 7.3 on study design focussing on recruitment, fieldwork and sampling and is complemented by deliverables focussing on other parts of study conduct like ethics, analytics and data management provided by other work packages.

This SOP provides a short overview on actions and documents that serve quality assurance in HBM studies.

Fieldwork of high quality is essential for receiving results that can be used for international comparisons between studies and over time. An improved instrument for such documentation is a so called **Fieldwork Manual**. It includes a detailed description of all steps of fieldwork and provides guidelines, checklists and instructions as well as Standard Operating Procedures (SOPs) during day-to-day business.

High quality of fieldwork is also closely connected with the ability of the interviewers to perform the interviews in an appropriate way. To put emphasis on this, the training of the interviewers is addressed in the second part of this SOP. Special background information to facilitate the interviewers' work is provided in the **Interviewer Manual**.

Another important part of quality assurance is quality control. **Quality control measures** encompass internal and external quality control, which are both necessary as it is the interest of all partners involved that fieldwork is performed in a harmonised and correct way. To warrant this, fieldwork has to be controlled and checked: the way to do this is described in the third part of this SOP.

Additional to the three above mentioned guidelines, SOPs for the Selection of Participants and Recruitment and specimen sampling are provided in the Annex 2.2 to Deliverable 7.3, an SOP for the exchange of biobanked samples is provided in Annex 1 to Deliverable 7.2. Any other SOP necessary for a proper conduct of a study in a selected country can be added to the Fieldwork Manual by the specific country.

1.1 Fieldwork Manual

The Fieldwork Manual is the most important document for the quality assurance of a study. Typically, the Fieldwork Manual for each study is prepared by the Survey Office at the very start of the study and is then used as a handbook throughout the phases of a survey. Because of its importance, a template for a Fieldwork Manual is included as Annex 2 in Deliverable 7.3. This template provides an overview about the most important points of fieldwork which should be described exhaustively to enable a repetition of the single tasks in exactly the same way. This template can only be an example as each study is different and requires individually prepared documents.

It is recommended that the unit responsible for each study starts preparing a Fieldwork Manual as soon as main decisions on the way the study shall be conducted are taken. A Fieldwork Manual is a "living document" until all procedures, steps and material are fixed. When it is finished, it is the main background document for all persons who have to be trained on the study. Feedback of the trainees should be integrated to update the Fieldwork Manual in the course of the study.

A well-elaborated Fieldwork Manual can also serve for regular quality checks of all procedures and builds the background for a subsequent study.

1.2 Training of the interviewers - Interviewer Manual

If a face-to-face interview is foreseen to be one of the instruments of the study it is important that the interviewers (it is advisable to employ more than one interviewer) all act equally as they are the ones who generate the requested data. To avoid an interviewer bias interviewers have to be trained on the content of the study. It is an asset if experienced interviewers can be engaged but still they have to be trained especially for each planned study. Basis for this is the Fieldwork Manual and training with fieldwork experts. It is important that the interviewers practise the conduct of the questionnaires and all parts of the home visit and sample taking (if applicable). Conducting test interviews is a perfect way to become familiar with the questionnaires. These test interviews should follow the exact procedure of the real interview, including the acceptance of the informed consent as the very first action when they meet the participant, the interview itself, the acceptance or taking of samples and the successful ending of the meeting, e.g. with a letter of thanks or a certificate and other incentives. It shall also be trained how to perform the interviews and on the demeanour of the interviewers.

Additionally to training on the interview situation directly, interviewers also need to understand the background of each question and memorise a way to react in case the participant does not understand a question. To this end, an Interviewer Manual to accompany the basic questionnaire developed for HBM4EU's first priority substances was created and can be found in the Annex 2.1.2.

To maintain quality during fieldwork it is advisable to compare once in a while the answers given to the different interviewers to some questions susceptible for interviewer bias. If a bias can be detected, another training and/or a different way of questioning has to be considered. In addition, interviewers are asked to keep a log-book. Positive and negative experiences shall be written down in the log-books and be exchanged with the other interviewers and with the members of the survey office to allow learning from each other.

At the beginning of the study already, criteria for quality targets have to be set and also include a guideline how to deal with potential errors. Both aspects are required to be part of the interviewer training.

If a study does not use a face-to-face interview there still will be a field team. Also these personnel has to be trained on all the procedures of the study – this can also be done with the Fieldwork Manual as background document for main study procedures and the Interviewer Manual as background document for the questionnaire.

1.3 Quality control measures

Quality control measures have to accompany all steps of study conduct. The main aim is to avoid and reduce mistakes. For this purpose, strategies to find mistakes in advance have to be applied. Fieldwork Manual, Interviewer Manual and SOPs shall be developed to avoid and reduce mistakes. These guidelines can also support to find mistakes if the correct performance is analysed on basis of these documents. Check lists to facilitate the control of the fieldwork can be developed, but they have to be adapted to the study in question. Internal quality control is done by the interviewers themselves, for the external quality control external controllers (e.g. from the survey office or especially hired ones) are necessary.

As already mentioned, proper handling of mistakes is important. Every error that has been detected in the process of control has to be documented and corrected immediately. Reasons for mistakes have to be evaluated by the survey office, a viable solution has to be found and the problem and its solution have to be communicated. If necessary, the respective parts (pages) of the Fieldwork Manual have to be updated.

1.3.1 Internal quality control

The goal of internal quality control is to ensure that every step of fieldwork is overseen (mostly) by the staff member in charge of performing the fieldwork her- or himself. Checklists are used to support training of the field teams.

These internal checklists should i.a. include:

1. Before start of field work check
 - ▶ of the transferred material/equipment necessary for conducting fieldwork
 - ▶ if all appointments for the sampling location have been fixed in advance and are compiled in the visit schedule
2. Before a home visit (resp. at centre) check:
 - ▶ the necessary documents to bring along
 - ▶ if everything required for a home visit has been adequately prepared
3. After a home visit (resp. at centre) check:
 - ▶ all documents: has everything been filled out and have all samples been taken, labelled and handled correctly?
 - ▶ have experiences been written down in the log-book?
4. Between home visits (resp. at centre) check:
 - ▶ function of the hot line, handling of last minute cancels, handling of the samples, data management etc.
5. At the examination centre check:
 - ▶ rooms and equipment of the examination centre

1.3.2 External quality control

External quality control is usually performed by institutions without involvement in the survey, e.g. other universities or private institutes to control the procedures. Especially for large population studies such an external control is essential. In smaller studies “external” quality control (or field visits) include the control of work of the field team members by researchers from the Survey Office responsible for the survey.

External quality control refers mainly to the conduct of the interview or the whole procedure in the context of a home visit. All steps laid down in the Interviewer and Fieldwork Manual can be used for a check, including the correct appearance and demeanour of the interviewer.

2 Related documents

Fieldwork Manual (see Annex 2 of Deliverable 7.3)

Interviewer Manual (see Annex 2.1.2 of Deliverable 7.3)

Other SOPs (see Annex 2.2 of Deliverable 7.3 and Annex 1 of Deliverable 7.2)



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Annex 2.2.3

SOP 3:

Procedure for obtaining human samples

WP7

Task 7.2

D 7.3

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This document has been created for the HBM4EU project. HBM4EU has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733032.

1 Introduction

Human biomonitoring is a powerful tool in the field of public health, although the lack of harmonization among the different HBM studies/programs can considerably limit the comparison of results, their global interpretation and subsequent translation into policy actions. Thus, in order to make possible an efficient use of the results of HBM studies is necessary to build a harmonized framework covering all stages of the HBM studies.

This guideline is intended to be used in the framework of the Human Biomonitoring Initiative (HBM4EU). HBM4EU has the aim to establish a European human biomonitoring platform and to fill knowledge gaps in representative exposure data. For the first year of the project a groups of substances have been selected: DINCH, phthalates, bisphenols, flame retardants, per- and polyfluoroalkyl substances (PFAS), PAHs, cadmium, chromium and aromatic amines. Appendix 3.1 describes the biomarkers and matrices included in the QA/QC scheme of the HBM4EU and thus, those biomarkers that will be analysed in the ICI/EQUAS in 2018.

The Standard Operating Procedure (SOP) for sampling provides an overview of the general procedure for the collection of human samples in human biomonitoring studies.

It is important to highlight that depending on the target chemical, additional treatments or precautions could be necessary. In addition, the definition of the minimum quantity of sample collected will depend on the amount required for subsequent chemical analysis which will in turn vary depending on the analytical method, the limit of quantification, etc. Therefore, these issues must be discussed previously and defined with the laboratory responsible for the analysis.

2 Precautions in the pre-analytical phase

The pre-analytical phase comprises all actions and aspects that occur prior to the analytical phase and should be considered as part of the laboratory works. This phase involves the sample collection, handling, transport and conservation, aliquoting and storage until the analysis.

Quality Control measures are commonly applied during the analytical phase by means of blanks, calibration curves, control samples, etc. in order to guarantee the reliability of their results. Control measures are often absent from the pre-analytical phase, however, all the precautions and controls measures taken during chemical analysis are useless if the samples have already been contaminated or altered during the previous steps such as sampling, transport or processing. Indeed, the pre-analytic phase has been identified as more error-prone than other intra and post-analytical steps^{1,2}

Control of the pre-analytical phase is even more important in human biomonitoring studies involving the general, supposedly non-exposed population than in other kinds of studies involving biological samples. On one hand, the type of samples analysed because when measuring an environmental chemical there is a risk of sample contamination due to the presence of this chemical in the environment. This is especially important in the case of ubiquitous chemicals that may even be present in the sampling material. On the other hand, the exposure to environmental chemicals usually occurs at low concentrations and their levels in biological matrices also tend to be low, thus meaning that the influence of a potential contamination on the results is high.

As such, it is essential to identify and avoid, or at least minimise, the possible sources of contamination. In this regard two main group of factors should be considered:

a) Influencing factors:

¹ Plebani M, et al. Performance criteria and quality indicators for the pre-analytical phase. *Clin Chem Lab Med.* 53:943-948. 2015.

² Plebani M. The detection and prevention of errors in laboratory medicine. *Ann Clin Biochem.* 47:101-110. 2010.

These factors are specific for each biomarker and are present before the sampling. The biological half-life of a chemical, alcohol consumption, medication intake or individual habits such as diet, are examples of influencing factors that can modify the levels of the chemical of interest. Therefore, the influencing factors for the target biomarker must be identified and a sampling strategy that takes them into account designed and finally considered during the results interpretation.

b) Interfering factors

These factors can modify the concentration of the biomarker after sampling due to different processes such as the external contamination, physical or chemical changes in the biomarker during transport or storage, or changes in the biological matrix (e.g. coagulation or sedimentation). In this case, it is essential to identify and avoid possible sources of contamination, such as exogenous contamination at the sampling location, contamination from the sampling equipment or vessels, or alterations due to absorption of the components to be analysed onto the walls of the vessel employed.

Although various different tools can be employed to control the pre-analytical phase, Standard Operating Procedures (SOPs) tend to be the most useful. A SOP is a clear, concise, comprehensive and detailed step-by-step written description of a sampling or recruitment procedure, analytical method, etc. Other control measures include the use of field blanks during fieldwork, the collection of replicate samples or the pre-cleaning of the sampling material or the control of the background contamination in sampling material.

The sampling SOP should also describe the measures for an unambiguous identification of the specimens and related documents (questionnaires, personal data, etc.) and conservation of the samples.

Finally, a written record of every event that occurs during sampling and all sample-related parameters (date and time of collection, volume, length, colour, etc.) will help in the identification of potential problems, for example, cross-contamination of a sample (e.g. urine sample contaminated with blood from menstruation). Additionally, a well-documented sampling procedure facilitates communication and avoids misunderstandings and errors within the fieldworkers' team and between fieldworkers and laboratory staff.

2.1 Urine

This biological matrix is the result of a filtration process that occurs in the kidneys to eliminate water-soluble toxins and waste from the body. Together with blood, urine is the biological matrix of choice in human biomonitoring studies as it is a non-invasive matrix, easy to collect and available in larger amounts than other matrices.

Spot urine samples are usually employed instead of 24-hour samples as the latter are more uncomfortable to collect and are more likely to become contaminated due to continuous opening of the vessel. When using spot urine samples, the variability in the volume of urine produced needs to be corrected since the concentration of endogenous and exogenous chemicals can vary significantly from void to void depending on the hydration status, time of last urination, etc. This dilution adjustment can be done by different methods, such as creatinine adjustment or specific gravity^{3, 4, 5}.

³ Cornellis R. et al. *Pure and Applied Chemistry*. 67:1575-1608.1995.

⁴ Barr DB. et al. *Environmental Health Perspectives*. 113: 192-200. 2005.

⁵ Aitio A. & Jarvisalo J. *Pure and Applied Chemistry*. 56: 549-566. 1984.

Although spot urine samples can be collected at any time of day, a first morning urine sample is recommended as otherwise the target biomarker may be below the LOQ due to sample dilution. A further possibility is to collect samples after at least 5 hours without urination.

2.1.1 Material needed for urine collection and storage

1. Urine collection vessels (120 ml polypropylene with a screw cap, pretreated and per-screened, see Appendix 3.2)
2. Labels
3. Latex or similar gloves
4. Sampling instructions for volunteers (Appendix 3.3)
5. Field blanks (120 ml polypropylene with a screw cap pre-treated filled with ~80 ml of purified water and handled as the real samples)

2.1.2 Sampling questionnaire for urine

The urine sampling should be accompanied by the collection of some basic information related to the urine sample and relevant questions that are necessary for the data interpretation.

The sampling questionnaire for urine should collect the following information:

1. Date and time of urine collection
2. First morning urine or not
3. If applicable, reasons for not collecting the sample
4. Time of the last urinate before urine collection
5. Time of the last meal before urine collection
6. Type of food consumed within the last 24 hours previously to the urine collection: fish, seafood, canned food, food packed in paperboard container, food packed in plastic bag, dried food, etc.
7. Observations

2.2 Blood

Blood is an ideal matrix for most chemicals because it is in contact with all tissues and is in equilibrium with the organs and tissues where chemicals are deposited. The collection of blood samples requires trained sanitary staff, special precautions related to the handling of biological material and commonly it requires an insurance contracting. Contrary to the urine sampling, the volume of blood that can be collected is quite limited.

Different types of blood samples can be collected. Samples of whole blood require additives to prevent the coagulation and both plasma and serum are derived from full blood that has undergone different biochemical processes after blood collection.

2.2.1 Sampling material

The number and type of blood tubes will depend on different aspects among them the target chemicals, the number of analysis or the LOQ of the analytical method employed.

1. Extraction tubes[†]:
 - Blood and plasma samples: tubes with anticoagulant.
 - Serum samples: tubes with no additives.
2. Regular phlebotomy needle or butterfly needle
3. Alcohol prep pads or wipes
4. Labels

5. Latex or similar gloves
 6. Sampling instructions for the medical staff performing the phlebotomy (Appendix 3.4)
 7. Field blanks (tubes filled with purified water and handled as the real samples)
- * *For the analysis of trace elements special tubes should be used to minimise the background contamination, e.g. Vacuette® Trace Elements 6 ml.*

2.2.2 Sampling questionnaire for blood

The blood sampling should be accompanied by the collection of some basic information related to the blood sample and relevant questions that are necessary for the data interpretation.

The sampling questionnaire for blood should collect the following information:

1. Date and time of blood collection
2. Number of tubes collected
3. If applicable, reasons for not collecting the required samples
4. Time of the last meal before blood collection
5. Type of food consumed within the last 24 hours previously to the blood collection: fish, seafood, canned food, food packed in paperboard container, food packed in plastic bag, dried food, etc.
6. Observations

2.3 Conservation, transport and storage of the samples

The deliverable report *D.7.2 "Strategy and SOPs for human sample exchange, including ethical demands"* includes all information related to the proper conservation and transport of the samples in human biomonitoring studies as well as the conditions of storage until the chemical analysis.

3 Specific recommendations for the substances in the 1st list of prioritization

Table 1 shows some recommendations for the selected group of substances regarding the pre-analytical phase. For its elaboration, WP9 experts and the CGLs were consulted.

Table 1. Recommendations for the groups of substances in the 1st list of prioritisation.

Recommendations	Group of substances			
	Phthalates	DINCH	Bisphenols	FRs
Sampling material				
<i>To avoid</i>	- Polyethylene terephthalate (PET), polyvinyl chloride (PVC)	- Polyethylene terephthalate (PET), polyvinyl chloride (PVC)	- Polycarbonate (PC), polyethersulfone (PES), polyethylene terephthalate (PET), polyvinyl chloride (PVC), epoxy resins	-
<i>Preferred</i>	- Polypropylene (PP)	- Polypropylene (PP)	- Polypropylene (PP)	- Polypropylene (PP)
<i>Pre-treatment</i>	- Wash with methanol - Decontamination with acid solution	-	-	- Material free of dust particles (rinse with methanol)
<i>Additives</i>	- No	- No	- No	- No
<i>Risk of contamination</i>	- Low/medium	- Low	- Low/medium	- Medium/high
<i>Precautions to minimize contamination</i>	- Precaution with non-oxidized monoester metabolites (MEP, MBzP, MiBP, MnBP, MCHP; MnPeP, MEHP, MnOP): take sampling blanks to account for onsite background values. - SOPs for sampling, test the background level in sampling material.	- SOPs for sampling, test the background level in sampling material, use of field blanks	- SOPs for sampling, test the background level in sampling material, use of sampling blanks	- Avoid the use of polystyrene (PS) packaging boxes - Be aware of dust as major source of contamination - SOPs for sampling, test the background level in sampling material, use of sampling blanks
Transport & conservation				
<i>Shipment</i>	- Cooled (2-8°C) or frozen If not cooling, not longer than 72h	- Cooled (2-8°C) or frozen If not cooling, not longer than 72h	- Cooled (2-8°C) or frozen	- Cooled (2-8°C) or frozen - - Avoid transport in polystyrene (PS) packaging boxes
<i>Biobank</i>	- Frozen, -20°C minimum, -80°C preferred	- Frozen, -20°C minimum, -80°C preferred	- Frozen, -20°C minimum, -80°C preferred	- Frozen, -20°C minimum, -80°C Preferred - Avoid polystyrene (PS) boxes
Related questions				
<i>Medical treatment</i>	- Are you taking medication in plastic capsules? - Please list the medications used - Dialysis, blood transfusion, blood donations (prior 24h)	- Are you taking medication in plastic capsules? - Please list the medications used - Dialysis, blood transfusion, blood donations (prior 24h)	- Dental fillings and inlays	
<i>Diet</i>	- Fasting period in the last 24h - Please mention if the food was packed and/or warmed in plastic containers	- Fasting period in the last 24h - Please mention if the food was packed and/or warmed in plastic containers	- Are you eating regularly canned food?/ Are you drinking regularly beverages canned? - Last meal eating canned food/beverages	Fatty fish consumption (BFRs)

			- Please mention if the food was packed and/or warmed in plastic containers	
Others	-	-	-	- Occupation - Use of computer and electronic equipment * Note: FRs are a very diverse group and there is a large number of possible sources of exposure

Recommendations	Group of substances			
	PFAS	PAHs	Anilines	Cd & Cr
Sampling material				
<i>To avoid</i>	- Teflon (Polytetrafluoroethylene, PTFE) and other fluoropolymers, glass	-	-	- Glass and metal
<i>Preferred</i>	- Polypropylene (PP)	- Polypropylene (PP)	- Polypropylene (PP)	- Urine: Polypropylene (PP) - Blood: special tubes for trace elements analysis
<i>Pre-treatment</i>	- No	- No	-	Urine: wash sampling material with 10% solution of HNO3
<i>Additives</i>	- No	- No	- As precautionary measure, 0.5 g citric acid per 100 mL urine should added to each sample container to avoid absorption of MDA, 2,4-/2,6-TDA.	- EDTA or heparin
<i>Risk of contamination</i>	- Medium	- Low	- High for aniline and o-toluidine	- Medium
<i>Precautions to minimize contamination</i>	- SOPs for sampling, test the background level in sampling material, use of sampling blanks - Precaution with dust particles	- SOPs for sampling, test the background level in sampling material, use of sampling blanks	- SOPs for sampling, test the background level in sampling material, use of sampling blanks	- SOPs for sampling, test the background level in sampling material (including needles used in venipuncture), use of sampling blanks
Transport & conservation				
<i>Shipment</i>	Cooled (2-8°C) or frozen	Cooled (2-8°C) or frozen	Cooled (2-8°C) or frozen	- Cooled (2-8°C) or frozen - Plasma: centrifugation and plasma removing is needed latest 24h after sampling - Red blood cells: centrifugation, plasma removing and three times washing with 0.9% NaCl solution is needed latest 24h after sampling

<i>Biobank</i>	Frozen, -20°C minimum, -80°C preferred	Frozen, -20°C minimum, -80°C preferred	Frozen, -20°C minimum, -80°C preferred	Frozen, -20°C minimum, -80°C preferred in PP material pre-treated with 10% solution of HNO ₃
Related questions				
<i>Medical treatment</i>	–	–	Recent use of acetaminophen, paracetamol, panodil	- Medication, contrast procedures in the pas 96h (Cr)
<i>Diet</i>	- Food eaten previous to the sampling - Consumption of microwave popcorn and packed fast food	- Barbeque	–	- Seafood consumption, canned food and drinks, vitamins and supplements containing Cr
<i>Others</i>	- Use of cosmetics, houseware, cleaning products, kitchen utensils, baking paper	- Smoking behaviour, black tattoos, traffic related exposure, occupational	- Smoking habits, occupational or environmental contact to isocyanate containing foams or glues and pesticides, hair dyes, tattoos.	- Smoking habits, occupation, piercing, jewellery, tattoos, implant, prothesis,

4 Appendix

4.1 Parameters included in the HBM4EU ICI/EQUAS 2018

SUBSTANCE GROUP	BIOMARKER	MATRIX
Phthalates	MEP	Urine
	MBzP	
	MiBP	
	MnBP	
	MCHP	
	MnPeP	
	MEHP	
	5OH-MEHP	
	5oxo-MEHP	
	5cx-MEPP	
	MnOP	
	OH-MiNP	
	cx-MiNP	
	OH-MiDP	
	cx-MiDP	
DINCH	OH-MINCH	Urine
	cx-MINCH	
Bisphenols	BPA	Urine
	BPF	
	BPS	
PFAS	PFPeA	Serum
	PFHxA	
	PFHpA	
	PFOA	
	PFNA	
	PFDA	
	PFUnDA	
	PFDoDA	
	PFBS	
	PFHxS	
	PFHpS	
	PFOS (sum of all isomers)	
	PAHs	
2-hydroxynaphthalene		
1,2-dihydroxynaphthalene		
2-hydroxyfluorene (2-FLUO)		
3-hydroxyfluorene (3-FLUO)		
9-hydroxyfluorene (9-FLUO)		

	1-hydroxyphenanthrene	
	2-hydroxyphenanthrene	
	3-hydroxyphenanthrene	
	4-hydroxyphenanthrene	
	9-hydroxyphenanthrene	
	1-hydroxypyrene (1-PYR)	
	3-hydroxybenzo(a)pyrene	
Flame retardants	BDE-47	Serum
	BDE-153	
	BDE-209	
	α-HBCD	
	γ-HBCD	
	DPHP	Urine
	BDCIPP	
	BCEP	
	BCIPP	
	TBBPA	Serum
	Syn-DP	
	Anti-DP	
	DBDPE	
	2,4,6-Tribromophenol	
Aromatic amines	MDA	Urine
	MOCA	
	Aniline	
	p-aminophenol	
	N-acetyl-4-aminophenol	
	p-PDA	
	o-toluidine	
	2,4-TDA	
	2,6-TDA	
Metals	Cadmium	Urine
		Blood
	Chromium	Red blood cells (erythrocytes)
		Urine
		Plasma

4.2 Pre-treatment/pre-screening of the vessels for urine sampling

Urine vessels should be washed with 10% nitric acid in purified water solution in order to eliminate background contamination of metals. The detailed procedure is shown below:

1. Prepare a 10% nitric acid solution from nitric acid 65% extra pure and purified water.
2. Put the solution in a tank.
3. Open the vessels and put vessels and lids into the tank. Ensure that all of them are completely immersed.
4. Vessels should be immersed in this tank at least for 3 hours (preferably overnight).
5. Take out the vessels from the acid tank and put them in a first tank with purified water. Shake for 2-3 minutes. Then, change the vessels and lids to a second tank of purified water. Shake for 2-3 minutes.
6. Take out vessels and lids and put them face down in a clean filter paper in order to dry them.
7. Once the drying is finished, lids are screwed to the resulting nitric acid pre-treated vessels. It is useful to make a mark indicating the minimum amount of urine required. Then, put the pre-treated vessel into a zip-lock plastic bag (or similar) in order to be sent to the survey office.

The acid solution can be reused until one month after its preparation. All the procedure must be done in a chemical fume hood with the suitable personal protective equipment.

To control the presence of contaminants, 5% of all urine vessels (after the cleaning procedure) have to be randomly selected. For this purpose, the vessels have to be filled with 200 ml purified water, shaken for 10 minutes, and aliquot has to be analysed for the biomarkers in question.

It is advisable to perform this screening for all the target biomarkers in order to identify background contamination.

4.3 Instructions for urine sampling

Please read carefully these instructions before taking the urine sample and do not use other vessel than the one provided.

1. Go to the bathroom.
2. Wash your hands carefully.
3. Open the vessel and place the screw cap with the top side down to avoid external contamination from dust.
4. Discharge the urine in the vessel until filled at least $\frac{3}{4}$ or until the minimum mark.
5. Screw the cap on tight.
6. Keep the sample at 4-8°C until you give it to the healthcare staff. Do not freeze the sample.

Thank you very much for your cooperation!

4.4 Instructions for blood sampling

1. Keep the specimen handling area clean and free of dust
2. Use only the supplies provided by the study responsible
3. Prepare the volunteer for phlebotomy, following your normal protocol, using alcohol to disinfect the collection site. Do not use solvent or other disinfectant products.
4. Fill completely the tubes to avoid the risk of haemolysis
5. After removing the tubes, invert them gently several times in order to mix the sample with the additive.
6. Sample treatment:
 - Plasma: centrifuge the sample to separate plasma from the cellular fraction. Carefully transfer the plasma into the vial avoiding transfer of the cellular components of blood. Place the cap on the vial tightly.
 - Serum: allow the sample to clot for at least 30 minutes but no more than 3 hours. Centrifuge the sample to separate serum from the cellular fraction. Carefully transfer the serum into the vial avoiding transfer of the cellular components of blood. Place the cap on the vial tightly.
7. Keep the samples vertically in the fridge at +4°C (max +10°C) until their transport according to the instructions defined in the *D.7.2 "Strategy and SOPs for human sample exchange, including ethical demands"*