



science and policy
for a healthy future

HBM4EU project

Documents of WP7 to support the
alignment within HBM4EU

(Study Protocol, Questionnaires,
Communication Material, etc.)

Where to find – how to adapt

Ulrike Fiddicke



2nd HBM4EU Training School 2018
Workshop for alignment of studies

Content

- Where to find documents of WP7
- Why and how to use and adapt
- What we are aiming at – the characteristics of an ideal HBM4EU study

Where to find documents on the HBM4EU webpage

www.hbm4eu.eu

The screenshot shows the HBM4EU website with the following elements:

- Header:** HBM4EU logo with the tagline "science and policy for a healthy future".
- Navigation Menu (Left):** ABOUT HBM4EU, THE PROJECT, STAKEHOLDERS, HBM4EU PRIORITY SUBSTANCES, RESULTS, TRAINING, CONTACTS, ONLINE LIBRARY, EVENTS, FUNDING OPPORTUNITIES, DATA MANAGEMENT.
- Main Content Area:** A large banner titled "COORDINATING AND ADVANCING HUMAN BIOMONITORING IN EUROPE TO PROVIDE EVIDENCE FOR CHEMICAL POLICY MAKING" featuring a family in a field.
- Calendar (Top Right):** CALENDAR | NOV 2018, showing a calendar grid for November 2018.
- Highlights (Bottom Right):** The 41st Mycotoxin Workshop in Lisbon on May 6 – 8, 2019: The conference will be organized by the Lisbon School of Health Technology.
- Results Section (Center):** A blue box labeled "RESULTS" with a red arrow pointing to it from the "RESULTS" link in the navigation menu. Below it are links for "NEWSLETTERS", "PUBLICATIONS", and "DELIVERABLES".
- Newsletters (Bottom Left):** Two newsletter thumbnails are shown: "Newsletter September 2018" and "Newsletter March 2018".
- Deliverables Section (Bottom Right):** A blue box labeled "Work package 7: Survey design and fieldwork preparation" with a dropdown arrow. Below it are four deliverables, each with a "Download" button:
 - Deliverable 7.1 Report on ongoing activities and existing data and data gaps for the 1st prioritised substances including a list of metadata that can be uploaded in IPCHEM
 - Deliverable 7.2 Strategy and SOPs for human sample exchange, including ethical demands
 - Deliverable 7.3 1st prioritisation Report on survey design: Study protocols, SOPs and Guidelines, tailored and transferred questionnaires for recruitment and sampling
 - Deliverable 7.4 1st material for communication to participants, including informed consent
- Footer:** A blue bar at the bottom with the text "This site uses cookies: Find out more" and a yellow arrow pointing to it.

2nd HBM4EU Training School, Nijmegen

Where to find documents on the HBM4EU webpage

www.hbm4eu.eu

The screenshot shows the HBM4EU website with a navigation menu on the left. A purple arrow points to the 'ONLINE LIBRARY' link in the menu. Another purple arrow points to the 'ONLINE LIBRARY' dropdown menu, which lists various document categories. A third purple arrow points to the 'Guidelines, protocols and SOPs (Standard Operating Procedures)' link in the dropdown. The main content area features a large image of a family and a calendar for November 2018. The 'ONLINE LIBRARY' section is expanded, showing a list of documents with download counts and dates.

HBM4EU science and policy for a healthy future

COORDINATING AND ADVANCING HUMAN BIOMONITORING IN EUROPE TO PROVIDE EVIDENCE FOR CHEMICAL POLICY MAKING

CALENDAR | NOV 2018

ONLINE LIBRARY

- GUIDELINES, PROTOCOLS AND SOPs
- BIOMARKERS
- LABORATORIES
- RESEARCH RESULTS
- TRAINING MATERIALS AND GUIDELINES
- SCOPING DOCUMENTS

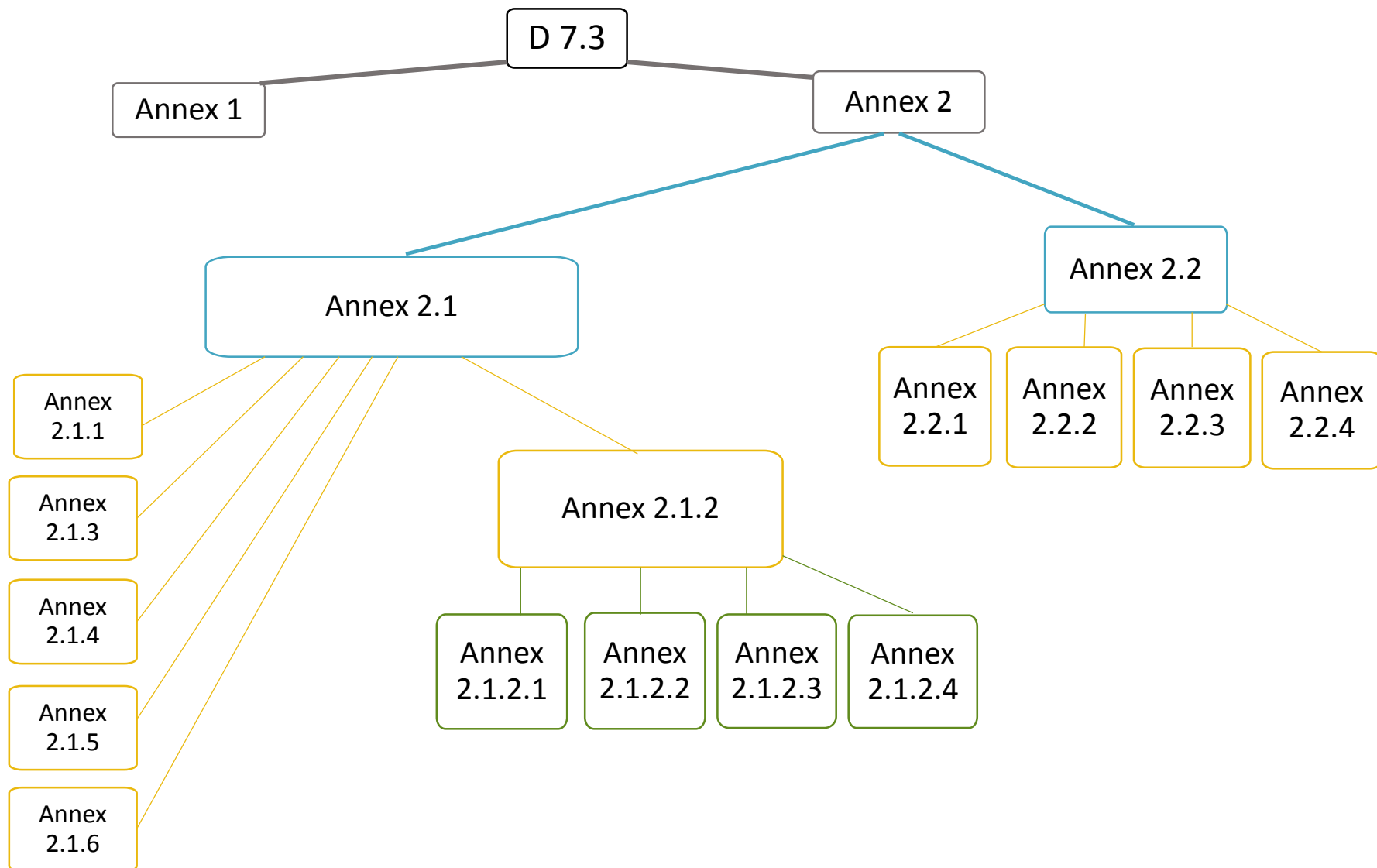
HBM4EU Library

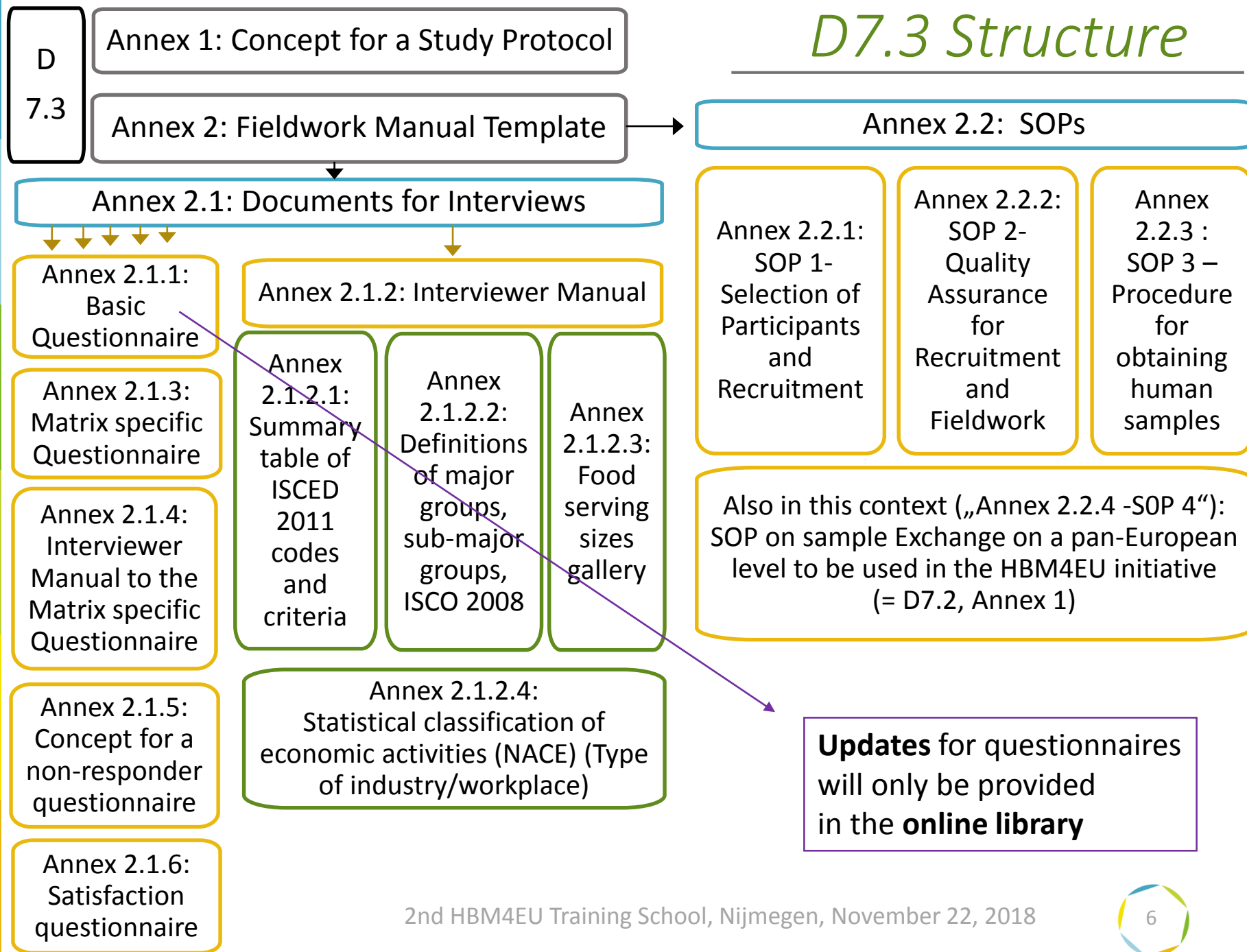
- Guidelines, protocols and SOPs (Standard Operating Procedures)
- Protocols and SOPs

Document Title	Downloads	Author(s)	Date	Action
Standard Operation Procedure (SOP) Shipment	234 downloads	Dominik Lermen (IBMT), Martina Bartel-Steinbach (IBMT), Frederik Gwinner (IBMT), Sabine Müller (IBMT)	23-01-2018 14:37	Download
Shipping Flowchart	179 downloads	Dominik Lermen (IBMT), Martina Bartel-Steinbach (IBMT), Frederik Gwinner (IBMT), Sabine Müller (IBMT)	23-01-2018 14:36	Download
Sample Transfer Protocol	165 downloads	Dominik Lermen (IBMT), Martina Bartel-Steinbach (IBMT), Frederik Gwinner (IBMT), Sabine Müller (IBMT)	23-01-2018 14:33	Download

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Structure of D7.3: 1st prioritisation report on survey design: Study protocols, SOPs, Guidelines and Questionnaires





D 7.3 Annex 2.1.1: Basic Questionnaire

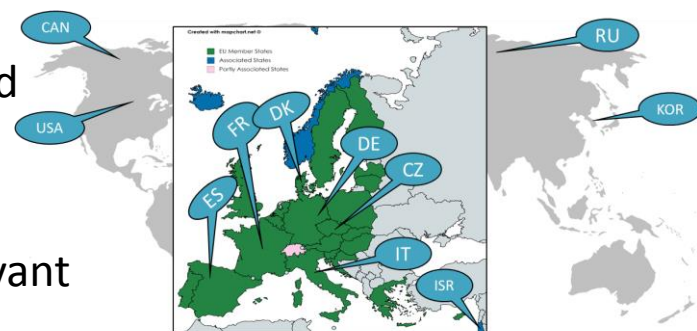
➤ Development based on:

- existing questionnaires of HBM4EU partners and
- questionnaires of international HBM studies

➤ Questions include questions on

1st priority substances (CGLs input!) and on relevant

- sociodemographic characteristics
- exposures to a range of compounds in the residential environment
- dietary habits
- lifestyles
- occupational exposures
- health status



7.3 Task Leader: Marina Lacasaña:
marina.lacasana.easp@juntadeandalucia.es

➤ New: end of 2018 (online library):

- Separate substance specific questionnaires for 1st and 2nd priority substances
- and age specific questionnaires (adults, adolescents, children)

D 7.3 Annex 2.1.1: Basic Questionnaire

Designed for **paper+pencil Face-to-Face interview** for adults

If other applications are planned adaptations are necessary.

BASIC QUESTIONNAIRE FOR 1st PRIORITY SUBSTANCES

QUESTIONNAIRE INFORMATION

ID (PARTICIPANT)	_____
ID (INTERVIEWER)	_____
DATE OF THE INTERVIEW	____/____/____
START TIME	____:____

Most questions used are closed questions:

- yes/no/don't know or very short answer
- easy and quick to answer
- provide facts
- easy to analyse

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"/>

Some are open questions (specify...):

- need a longer answer and ask the respondent to think and reflect
- give opinions and meanings
- provide more information
- more difficult to analyse

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.....			

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"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Answer categories are disjoint

D7.3 Annex 2.1.2: Interviewer Manual (for Basic Questionnaire)

I. SOCIO-DEMOGRAPHIC SECTION

QUESTIONS	JUSTIFICATION	INFORMATION FOR INTERVIEWERS
1. What is your birth date?	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).	Month and year of birth will be asked here.
2. Where were you, your parents and grandparents born?	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).	In this question, information on countries where the participants and their direct family members (parents and grandparents) were born will be asked for.
3. Which language(s) do you speak at home	Asking for languages spoken at home we can collect additional information on the origin of the participant and also on cultural factors.	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).
4. How long have you been living in...? Please indicate the number of years (or months if less than 1 year)	This question is intended to gather information on internal and external migrations, since it could be associated with changes in chemical exposure levels.	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.
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)	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.	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.

Develop new questionnaires in the frame of HBM4EU

- Base new questionnaires on the HBM4EU questionnaires
- Keep changes for translation /adaptation to the country as small as possible to safeguard harmonisation!

Support: WP8 help desk via HBM4EU homepage:

<https://www.hbm4eu.eu/private/targeted-field-work-wp-8/>

or email to: helpdesk-HBM4EU@phe.gov.uk

- Questions are forwarded to Task 7.3 /Task 10.3 to discuss changes and finally safeguard a harmonized data analysis
- New questionnaires shall be approved by Task 7.3/Task 10.3

Translation and adaption of questionnaires

➤ **Two independent careful translations**

1) Translation expert

→ supporting documents: Interviewer Manual

2) Scientific (HBM) expert

→ control if translation matches with intentions

→ adaptations to national needs



➤ Please **document differences** to the recommended HBM4EU questionnaires and ask for their approval!

➤ Run at least **5 test interviews**

D7.3 Annexes 2.1.3 – 2.1.6: Other questionnaires

1) Annex 2.1.3 + 2.1.4

Matrix-specific questionnaire (1st prio subst.)

+ specific Interviewer Manual

to collect information on 24-72 h before sample taking



2) Annex 2.1.5

Concept for a Non-responder questionnaire

to collect characteristics of invitees who decided not to participate needed to calculate selection biases



3) Annex 2.1.6

Satisfaction questionnaire

to collect information on acceptance of single instruments to learn for a follow-up

D 7.2: Strategy and SOPs for human sample exchange

Templates provided by Task 7.4

Task Leader: Dominik Lermen: dominik.lermen@ibmt.fraunhofer.de

See presentation on transport of samples

D7.4: 1st material for communication to participants

Templates from Task 7.5 Communication to Participants

Task Leader: Andromachi Katsonouri: akatsonouri@sgl.moh.gov.cy

1. Invitation letter
2. Information leaflet, including info on study, role of participants, chemicals
3. Reply cards
4. Reminder letter
5. Thank you letter (for persons interested to join the study, but are ineligible)
6. Fact sheets on chemicals
7. Appointment letter
8. Pre-visit letter
9. Certificate of informed consent
10. Withdrawal form
11. Thank you letter
12. Report of personal results



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GOVERNMENT / INSTITUTE LOGO



<Institute Name>
<Institute Address>
Email: < Responsible person>
Tel.: <of responsible person>
FAX: <of responsible person>

Prospect code: <XXX> Date <00 Month 20XX>

<Mr. / Ms. First Name Last Name>
<Street Address>
<Town/City POSTCODE>

Invitation to join the human biomonitoring study HBM4EU

How exposed are you to hazardous chemicals? Help us find out and let's create a healthier future in [Europe/your country] together

Dear Mr. / Ms. [Last Name],

We would like to invite you to take part in HBM4EU (Human Biomonitoring for Europe), a study which aims to investigate people's exposure to [environmental chemicals]. In [your country], the [Ministry of country's] (Program Owner) is responsible for leading this study.

Your participation is vital and will help to control people's chemical exposure nationally and across Europe through laws and interventions. By engaging with participants like you, HBM4EU will help to raise awareness among the public and promote actions to prevent exposures to harmful chemicals.

You have been randomly selected to participate, together with [XX] European citizens from [YY] different European countries. Representativeness and usefulness of the results of the study will depend on people we contact to get involved. It will take [XX] of your time to provide [samples] and complete a questionnaire. Your participation is voluntary and you can opt out at any time.

Your personal information and samples will be coded and anonymized to protect your privacy. You can find out more about the study by reading the enclosed leaflet or <https://www.hbm4eu.eu/>.

Please complete and return the appropriate enclosed reply card by [insert date] to confirm/refuse participation.

Please do not hesitate to contact us should you have any concerns or wish to discuss further.

Thank you for your time. Without your participation, we cannot succeed in creating a healthier future for everyone in Europe.

Yours sincerely,

[Title and Name of the Principal Researcher]
[Signature of responsible person]

Green Reply Card: "I want to participate"

Thank you for taking time to consider the information for participation in this HBM4EU study and for your interest to participate.

Please complete the following information to help us check whether you fulfil the study's eligibility criteria for participation and to indicate how you prefer to be contacted for organising an appointment with our research team.

Your information will be held confidential and used only for the purposes of determining your eligibility and organising an appointment.

First Name: _____ Surname: _____
Address: _____
Phone number: _____
Email: _____

Eligibility criteria will be adjusted for each individual HBM4EU study.

Some Possible criteria:
Age _____
Sex _____
Years of residence in area _____

I prefer to be contacted in the following way (please mark/initial all that apply):

☐ By phone

The most suitable day and time you can reach me is:

Day	Time availability	Most preferable day and time (Please indicate with "X")	
	FROM (HH:MM)	TO (HH:MM)	
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			

☐ By email
☐ By post

Please return this reply card to [Specify person and contact only by Local's Name]

Orange Reply Card: "I do not want to participate"

I am not interested in participating in the HBM4EU Study.

Thank you for taking time to consider the information for participation in this HBM4EU study.

Please help us understand how the people who choose not to take part in the study compare to the people who want to take part, by answering the following questions.

Your information will be held confidential and will be used solely for this and audit purposes and to improve future studies.

(This questionnaire must be appropriate for each HBM4EU survey and justified to ask. This will be determined in consultation with the leader of the particular survey)

First Name: _____ Surname: _____ Address: _____ Phone (if appropriate): _____

Please tick on all that apply. If you feel uncomfortable answering a particular question, you may skip it.

1. How old are you (for this study)?
☐ 11 years ☐ 12 years

2. My job is:
☐ I am a housewife/househusband for this particular HBM4EU study

3. My current status is:
☐ employed ☐ unemployed (only specify) ☐ retired ☐ looking for work ☐ unable to work ☐ studying ☐ housekeeping

4. My highest level of education is:
☐ elementary ☐ high school ☐ undergraduate ☐ graduate / professional

5. ☐ I smoke ☐ I don't smoke

6. ☐ I'm in good health ☐ I have health problems

7. I do not wish to participate in this study because (Please check all that apply):
☐ I don't have time ☐ I am not interested in the subject ☐ I don't like what I would need to do
☐ I don't see a value for me ☐ I don't see a value for society ☐ I don't like to visit the study organizers ☐ Other (specify) _____

D7.4: 1st material for communication to participants

Templates from Task 7.5 for occupational study:

Exposure of workers to hexavalent chromium and other hazardous chemicals

1. Leaflet with information for workers
2. Consent form for participating workers
3. Factsheet “Working safely with chromium”
4. Leaflet with information for employers
5. Consent form for employers

Characteristics of an ideal HBM4EU study

Study population

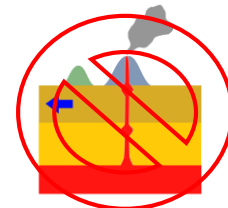


6-11 y
12-19 y
20-39y

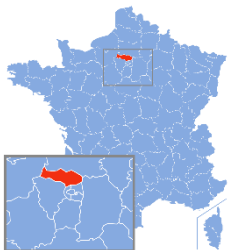
150 m
+
150 f

≡ SES /
levels of
urbanisation

🏠 ≥5y
4 Seasons



Sampling frame



preferably population registries, or randomly selected schools, etc.
Preferably national representative

Study instruments

BASIC QUESTIONNAIRE FOR 1st PRIORITY SUBSTANCES	
QUESTIONNAIRE INFORMATION	
ID (PARTICIPANT)	_____
ID (INTERVIEWER)	_____
DATE OF THE INTERVIEW	_____
START TIME	_____
END TIME	_____
PLACE	_____



Source: angellodeco / Fotolia.com

First morning urine/
blood (biobank-80°C)

Additional measures:
matrix-specific ques.; non-responder q.
follow SOPs, perform quality control

Communication: to safeguard high response rate; incentives?

Analytics: in labs that passed HBM4EU QA

Sharing of data and samples → Pseudonymisation → GDPR

Results: individual results to calculate European Reference Values → informed consent!!

Quality assurance and control methods for fieldwork

- National study protocol
 - describes the study in detail (background information for all)
- Fieldwork Manual
 - for **training** of the staff and every-day-use (**repeated training!!**)
 - includes SOPs for all essential procedures
- Log-books for field staff
 - to transmit experiences collected during single participant visits, to learn from each other
- Check lists
 - to prepare home visits, listing all material for one participant
- Regular field visits of internal or external auditors
 - according to check lists for internal and external field visits



Source:
<https://openclipart.org/detail/169719/checklist>



Umwelt
Bundesamt

Thank you for your
attention!

ulrike.fiddicke@uba.de

Speaker's information

Ulrike Fiddicke has been working for the German Environment Agency, Berlin, Germany, since 2010. She already worked within COPHES and DEMOCOPHES in the area of study design and fieldwork. She received training in nutrition science and public health. In HBM4EU she is responsible for study design and fieldwork preparation, leads WP7 and Task 7.2.



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