Questionnaire on human biomonitoring (HBM) for risk assessment purposes

Human Biomonitoring (HBM) is an important tool to survey the body burden of humans resulting from exposure to chemicals via different routes (lung, skin, digestive tract). Inclusion of HBM data could improve human health risk assessment of general people (exposure via air, drinking water and food) as well as workers, by providing more accurate data on exposures. In addition, by using HBM it could be possible to make direct linkage between internal exposure and AOPs (adverse outcome pathways) resulting in adverse health effects. Especially if the pollutant has a cumulative effect, and e.g. if the working conditions (personal protection equipment, inter-individual differences in respiratory ventilation, etc.) determine large differences in internal dose between individuals that are not taken into account by atmospheric metrology biomonitoring has proven its usefulness.

EU-funded project, HBM4EU, aims to develop new European wide biomonitoring based exposure data and exposure-health effect relationships based on internal exposure biomarkers and effect biomarkers for use in the risk assessment of chemicals. The ultimate goal is to improve human risk assessment of priority chemicals and mixtures by more efficient application of HBM. In order to achieve this goal, the current risk assessment practises in different countries and the current use of human biomonitoring in risk assessment of chemicals are evaluated. Therefore, we invite risk assessors, working under different regulatory contexts, to answer the short questionnaire on the use of HBM in risk assessment of chemicals.

You can exit the questionnaire at any time and return later to complete or revise the answers. To do so, please choose "Save & Continue later" and carefully record the address of the return link. After the last page you'll get to the summary page where you can review your answers. To submit the questionnaire click "Finish" at the bottom of the summary page.

Responses will be treated with confidentiality and sensitivity by the researchers. Gathered data will only be used for the purpose of research within HBM4EU and will be presented in an anonymised form.

Information on the person filling in the questionnaire:

Name:

Job title:

Organisation:

Country:

Under which regulatory framework are you working? Please select one or more options.

- REACH
- Food
- Occupational health and safety
- Cosmetics
- Plant protection products
- Biocides
- Circular economy and material cycles
- Other, please, specify:

If you are working only in the field of occupational health and safety, select "Yes" to move to the questions addressing only those aspects. If your work is divided to other fields as well, select "No" to continue to the questions on human biomonitoring on general population.

QUESTIONS

1. Considering the regulatory field you are working, is human biomonitoring regularly applied in your country?
    - Yes
    - No
    - Only limited extent, please explain

2. Is there any guidance (regulatory, institutional) for the use of human biomonitoring data for risk assessment in your country?
    - Yes
    - No
    - Don’t know

    Please describe further (you can also give links to relevant material/references):

3. If applicable in your country, what are the main drivers to start human biomonitoring campaign in general population? Select at maximum three main drivers.
    - Confirm exposure to a specific substance
    - Assess the magnitude of internal exposure to a substance
    - Health Surveillance
    - To support risk assessment and define priorities for intervention
    - To support risk management measures
    - To confirm data from environmental monitoring/modelling campaigns
    - Other, please specify
    - Do not know
    - Biomonitoring is not usually performed in my country

4. In your country, is there any specific guidance for the technical and organisational application of HBM?
    - Yes, please, describe:

- No
- Do not know

5. In your opinion, how could human biomonitoring best contribute to risk assessment/ management and possibly, in a few years from now, with new developments? Select three most important aspects
    - Providing realistic exposure data
    - Historical/retrospective exposure data
    - Combining different exposure routes –> estimate total internal exposure
    - Integrate single chemical exposure due to presence in various products or products and workplace atmosphere (aggregate exposure)
    - Assess combined exposure such as in Common Assessment Groups (CAG) as used for pesticides (combined exposure assessment), e.g. by measuring a similar or identical metabolite
    - Prioritization of risk management / policy / intervention
    - Assessing temporal exposure trends
    - Assessing effectiveness of policy/risk management actions
    - Characterizing geographical patterns of exposure or effect
    - Comparing different population subgroups and identifying vulnerable subpopulations
    - Using more biological effect markers in biomonitoring to detect early effects
    - Other, please describe:

6. In your country, do you or have you used *DNA or protein adducts as* a marker of exposure in the risk assessment?
    - Yes
    - No
    - Don’t know

7. In your country, do you or have you used *biomarkers of effect (including e.g. “omics”-based markers)* in the risk assessment?
    - Yes
    - No
    - Don’t know

8. What are your criteria for using human biomonitoring data in risk assessment? Please tick all relevant
    - Existence of validated method for biomonitoring
    - Existence of health based biological limit/guidance values (BLVs/BGVs)
    - If it is possible to calculate biomonitoring equivalents for health based limit values (e.g. for ADIs/TDIs)
    - Existence of biological reference (background/normal) values
    - Sufficient population size
    - Human biomonitoring level can be related to the exposure source
    - Biomonitoring level can be directly related to the health effects
    - Other, please specify

9. According to your experience, how often your criteria for using human biomonitoring data in risk assessment can be fulfilled?
    - Always
    - Very often
    - Often
    - Sometimes
    - Rarely

10. In your country, are HBM results of the general population usually compared to biological limit values (BLVs)/biological guidance values (BGVs) or reference values set for general population?
    - Yes, to health based BLVs or BGVs
    - Yes, to reference values or population distribution based BGVs
    - Yes, both
    - None of these

11. Please specify the substances for which there is a BLV or a BGV in your country? You can also provide a link to the list of BLVs or attach a list as an attachment.

12. What is the status of these values?
    - They are binding limits given by the law. Additional information (optional):
    - They are indicative limit values given by authorities. Additional information (optional):

- They are recommendations of the laboratory/research institute. Additional information (optional):
- Other, please, specify.

13. For the substances for which no BLV or BGV exists, what references do you use to interpret data (e.g. BLV or BGV from other countries)?

14. Is there work going on to elaborate health based limit values for general population in your country:
    - Yes
    - No
    - Do not know

15. What are the important obstacles you face when applying biomonitoring data in the risk assessment of general population? Please fill in matrix for the chemicals in general and for the following priority compounds. Notice that the table needs to be scrolled to the right to see the rest of the columns!

	Chemicals (in general)	Phthalates/DINCH	Bisphenols	Per-/Polyfluorinated compounds	Flame Retardants	Cd, Cr	PAHs and air pollutants	Anilin family, e.g. MOCA	Chemical mixtures (pesticide mixtures)	Emerging chemicals
No need, the current exposure data is sufficient										
There is no official guidance for HBM use										
There is no enforcement										
Unknown how to interpret or use biomonitoring data										
No validated methods										
No guidance values or background/normal values										
Human biomonitoring level cannot be related to source										
Information on what is really in the human body might lead to public arousal/anxiety										
Ethical aspects such as acquiring informed consent										
Other, please specify below										
None										

16. In case it is possible to perform a health impact assessment based on HBM data, do you think this could be of additional value to assess certain policy goals (prospective and retrospective)? If yes, can you give an example?

17. How do you communicate biomonitoring data in case of general population? Tick all options that apply.
    - Communicate to the person tested
    - Communicate to the health care
    - National Authorities in the scope of Health Programs
    - Other, please specify
    - Not communicated

QUESTIONS SPECIFIC FOR OCCUPATIONAL SAFETY AND HEALTH

Following questions are specific for the use of biomonitoring in occupational risk assessment at workplaces. If you work also in this field, please continue answering also these questions. If not, we thank you for your replies.

1. Is human biomonitoring regularly applied in your country in occupational safety and health?

    - Yes
    - No
    - Only in limited extent, please explain

2. Is there any guidance (regulatory, institutional) for the use of human biomonitoring in the risk assessment at workplaces in your country?
    - Yes
    - No
    - Don’t know

    Please describe further (you can also give links to relevant material/references):

3. If applicable in your country, what are the main drivers to perform biomonitoring at occupational settings (select at maximum three main drivers)?
    - Confirm exposure to a specific substance

- Assess the magnitude of internal exposure to a substance
- Health Surveillance performed by occupational health care
- To support risk assessment and define priorities for intervention
- To support risk management measures
- To confirm data from air monitoring/modelling
- Regulations (e.g. B-Pb measurements given by law)
- Other, please specify
- Do not know
- Biomonitoring is not usually performed in my country

4. If one of the main drivers to perform biomonitoring at workplaces is health surveillance made by occupational health care, are the data available for the use in the exposure assessment and management at the workplace?
    - Yes
    - No, explain why:
    - Varies, please, explain:
    - Do not know

5. In your country, is there guidance for the application of human biomonitoring in workplaces/occupational health care?
    - Yes, please, describe (you can also give links to respective guidance):
    - No
    - Do not know

6. According to your view, are current regulations in your country effective enough to support the use of biomonitoring in occupational health and safety?
    - yes
    - no, explain why?
    - do not know

7. In your country, do you recommend the use of some *DNA or protein adduct analyses* as a marker of exposure in occupational biomonitoring?
    - Yes

- No
- Don’t know

If yes, specify:

8. In your country, do you recommend the use of some *biomarkers of effects (including e.g. “omics”-based markers)* in occupational biomonitoring?
    - Yes
    - No
    - Don’t know

    If yes, specify:

9. In your opinion, what are the criteria for using human biomonitoring data in risk assessment at workplaces? Please tick all relevant.
    - Existence of validated method for biomonitoring
    - Existence of health based biological limit/guidance values (BLVs/BGVs)
    - Existence of biological reference (background/normal) values
    - Biomonitoring levels can be related to the exposure source
    - Biomonitoring level can be *directly* related to the health effects
    - Other, please specify

10. Are biomonitoring results of workers compared to biological limit values (BLVs)/biological guidance values (BGVs) or reference values?
    - Yes, to health based BLVs/BGVs
    - Yes, to reference values or population distribution based BGVs
    - Yes, both
    - None of these

11. Please specify the substances for which there is a BLV or a BGV? You can also provide a link to the list of BLVs or attach a list as an attachment.

12. What is the status of these values?

- They are binding limits given by the law. Additional information (optional):
- They are indicative limit values given by authorities. Additional information (optional):
- They are recommendations of the laboratory/research institute. Additional information (optional):
- Other, please, specify?

13. For the substances for which no BLV or BGV exists for workers, what references are used to interpret data (e.g. limit values from other countries)?

14. Is there work going on to elaborate health based limit values for workers in your country:

- Yes
- No

15. What are the important obstacles you face when applying biomonitoring in occupational risk assessment? Please fill in matrix for chemicals in general and for the following priority compounds.

	Chemicals (in general)	Phthalates/DINCH	Bisphenols	Per-/Polyfluorinated compounds	Flame Retardants	Cd, Cr	PAHs and air pollutants	Anilin family, e.g. MOCA	Chemical mixtures (pesticide mixtures)	Emerging chemicals
No need, the current data is sufficient										
There is no official guidance for HBM use										
There is no enforcement										
Unknown how to interpret or use biomonitoring data										
No validated methods										
No guidance values or background/normal values										

Human biomonitoring level cannot be related to occupational source										
Information on what is really in the human body might lead to public arousal/anxiety										
Ethical aspects such as acquiring informed consent										
Other, please specify below										
None										

16. How occupational biomonitoring data is usually communicated in your country? Tick all options that apply.
    - Results are communicated directly to the worker
    - Results are communicated to the Occupational Health Service
    - An overview of the results is communicated directly to the employer
    - Communicated to the national authorities
    - Other, please specify
    - Not communicated

17. Has occupational health service an obligation to give an overview of the biomonitoring results to the employer?
    - Yes
    - No
    - Do not know

18. Please, elaborate how the results are communicated to the employer (by company/plant, by task, are statistical data provided).