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Use of biomonitoring in occupational risk assessment – results from the HBM4EU survey and good examples

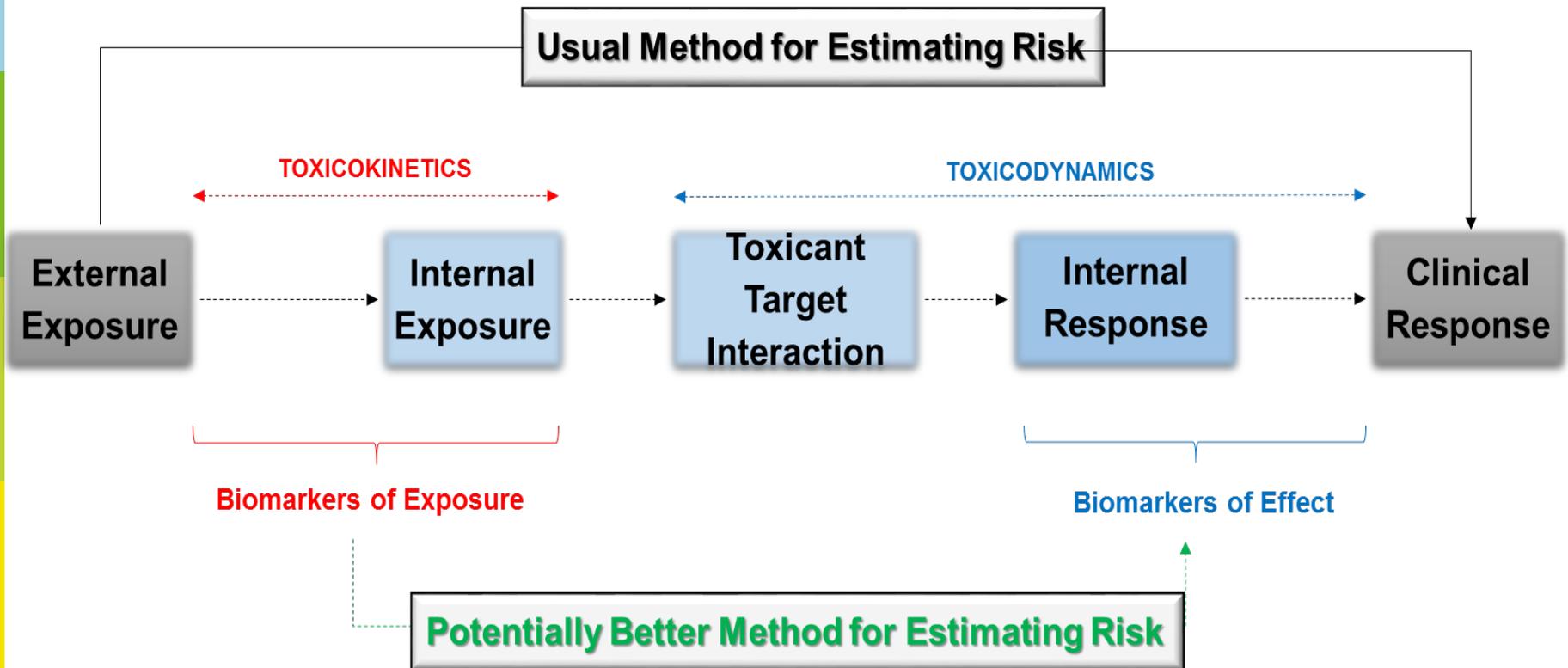
Roadmap on Carcinogens, 27-
28.11.2019

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Occupational Health

Background

- In the human health risk assessment (RA) of chemicals, the default approach is either
 - to consider only external exposure or
 - to infer internal exposure from the external exposure measurements from different sources and via different routes (inhalation, dermal absorption, ingestion) by modelling.
- This approach embraces various uncertainties, and may be improved by inclusion of HBM data.

Improving RA with HBM



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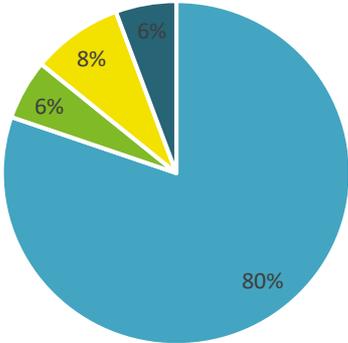
One of the most important aims of the HBM4EU project is to enhance the use of human biomonitoring data in risk assessment and human impact assessment of chemicals in different regulatory contexts.

To support this aim **current risk assessment practices in different regulatory contexts were evaluated** and a **survey was conducted** to gather information from national regulatory risk assessors on their risk assessment practices, the use of human biomonitoring, and the possible obstacles related to its use.

In addition, the review of the available risk assessment methodology was performed in order to find out how biomonitoring has been recognized and advised to be used in the human risk assessment

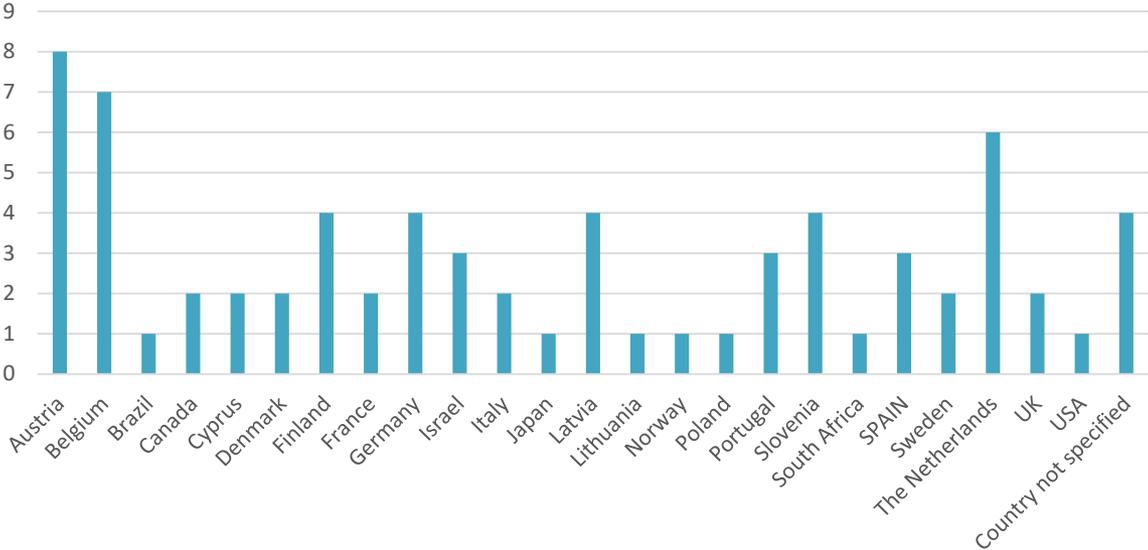
Survey to national risk assessors/authorities

Countries distribution



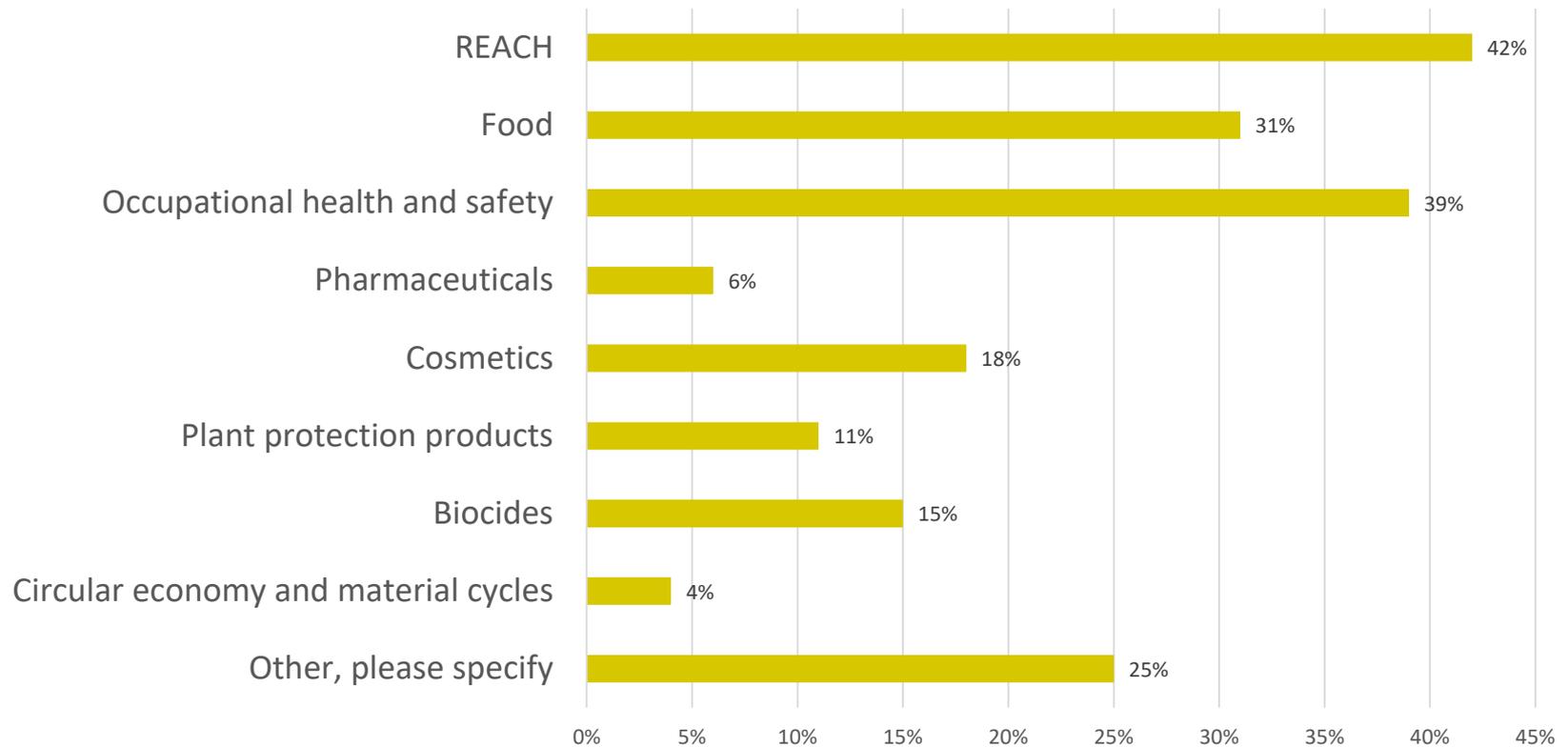
- EU
- Non-EU (European countries)
- Non-European
- Country not specified

Respondents per country total n=71



Regulatory fields covered

Regulatory frameworks of the respondents

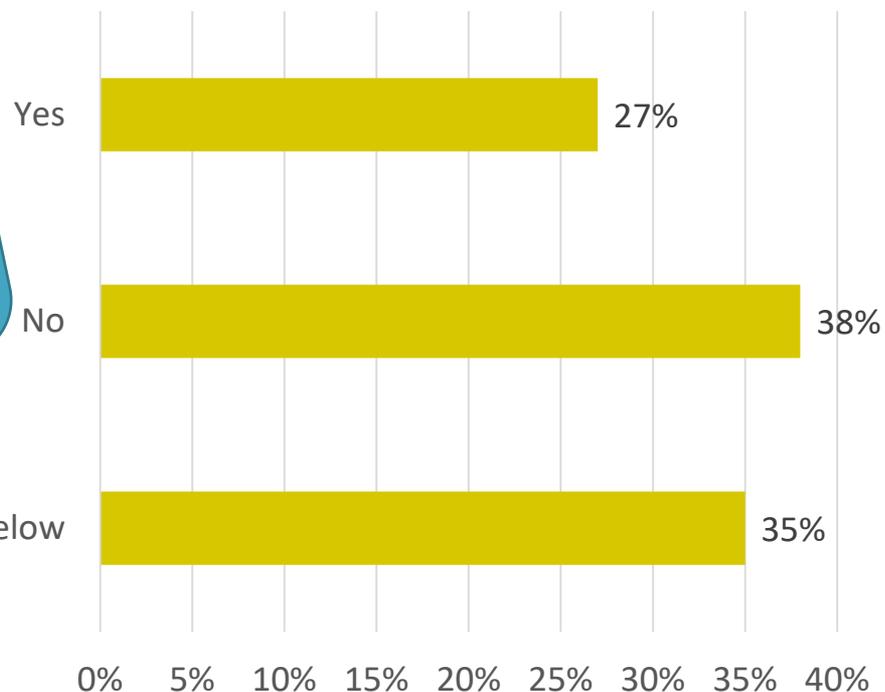


Biomonitoring is not regularly applied in the risk assessment in general

Considering the regulatory field you are working, is human biomonitoring regularly applied in your country?

In occupational health 60% considered that it is regularly applied – however in some countries it is only limited to P-Pb

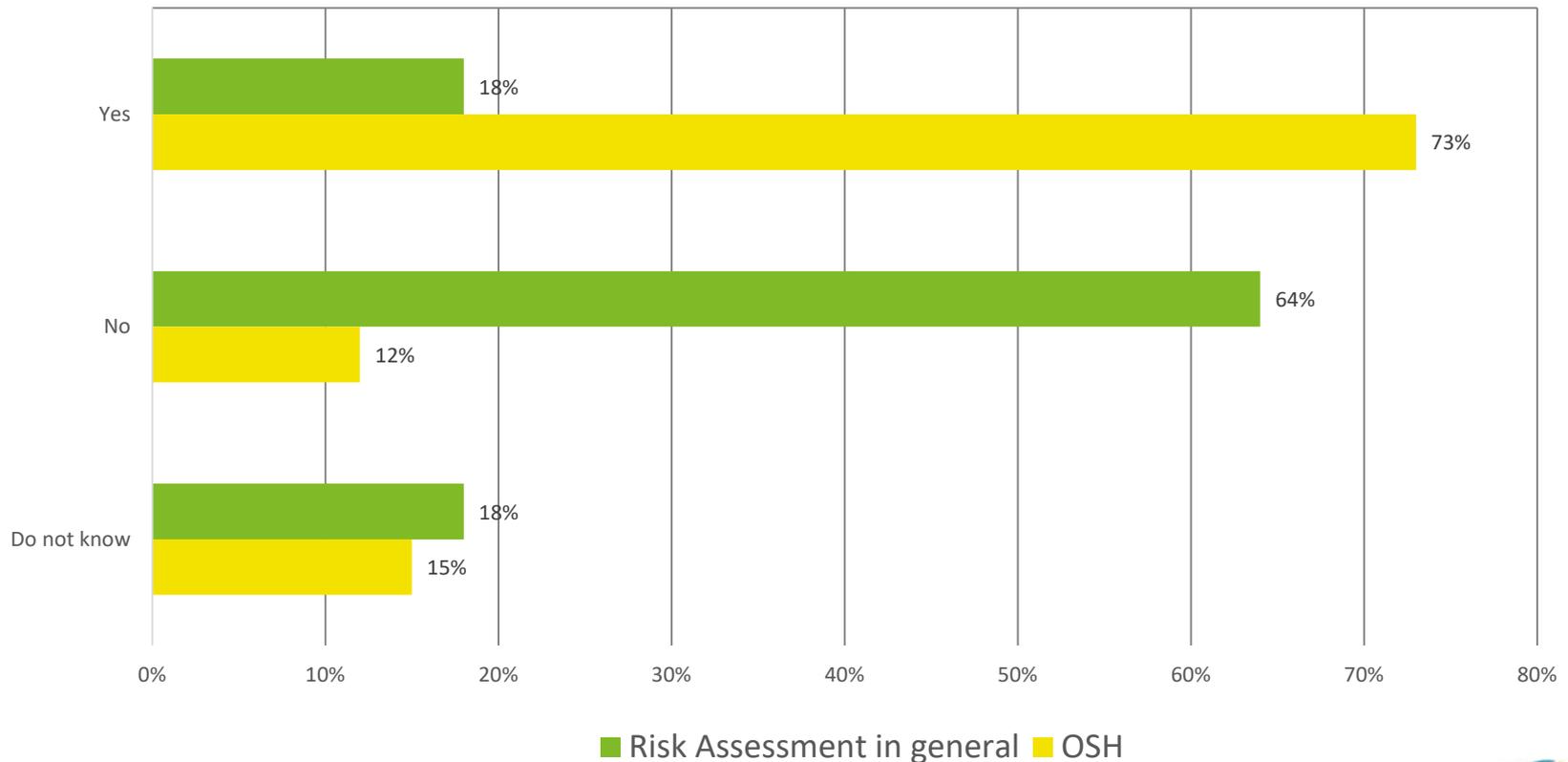
Only in limited extent, please explain below



Total N=55

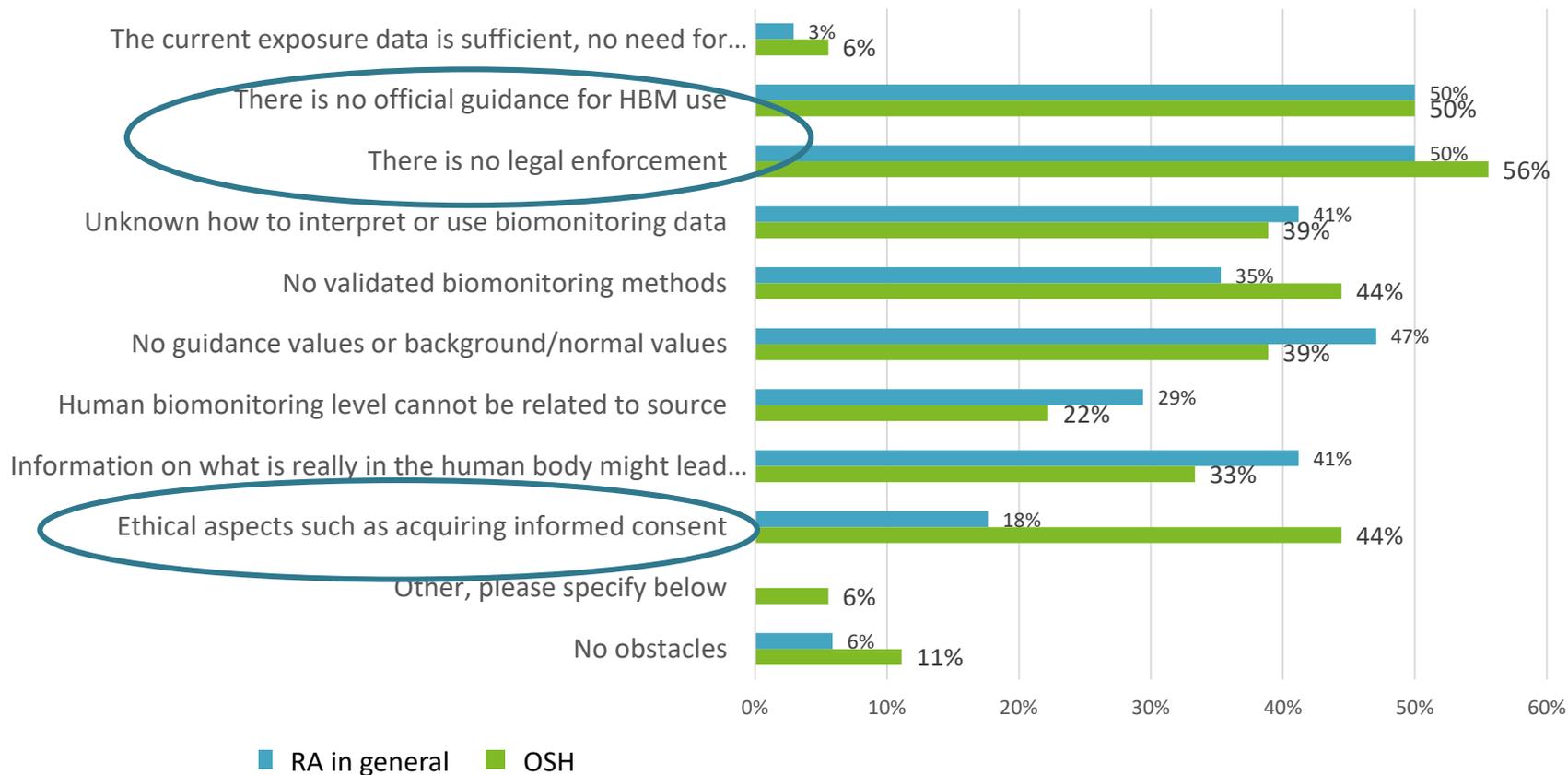
Lack of guidance was commonly reported

Is there any guidance (regulatory, institutional) for the use of human biomonitoring data for risk assessment? (n=55 for RA in general, n=22 for OSH)



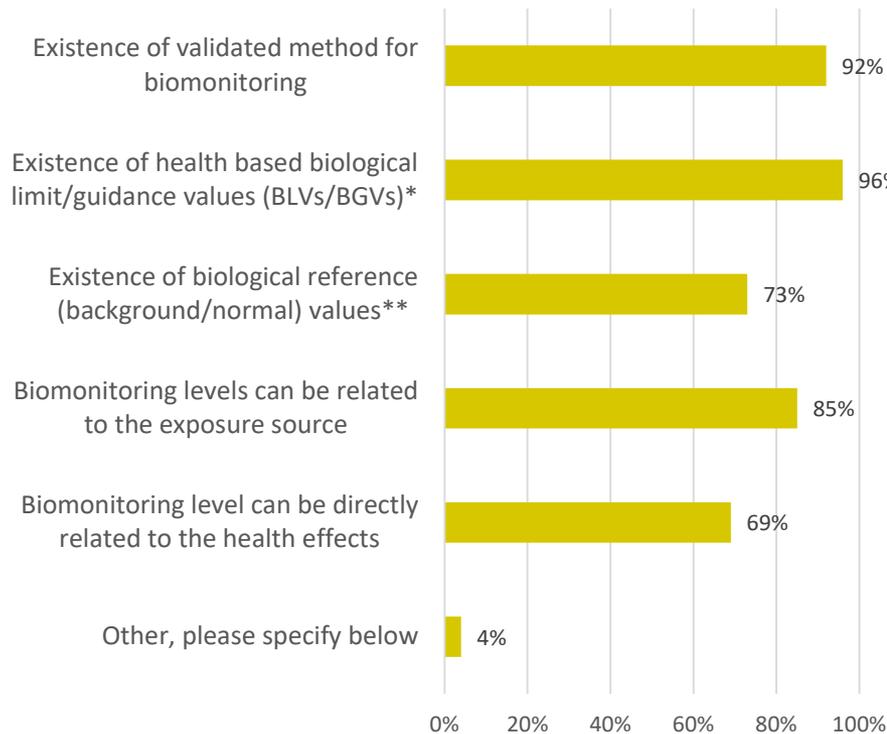
Need for the development of the guidance and supporting legislation

What are the important obstacles you face when applying biomonitoring data in the risk assessment?

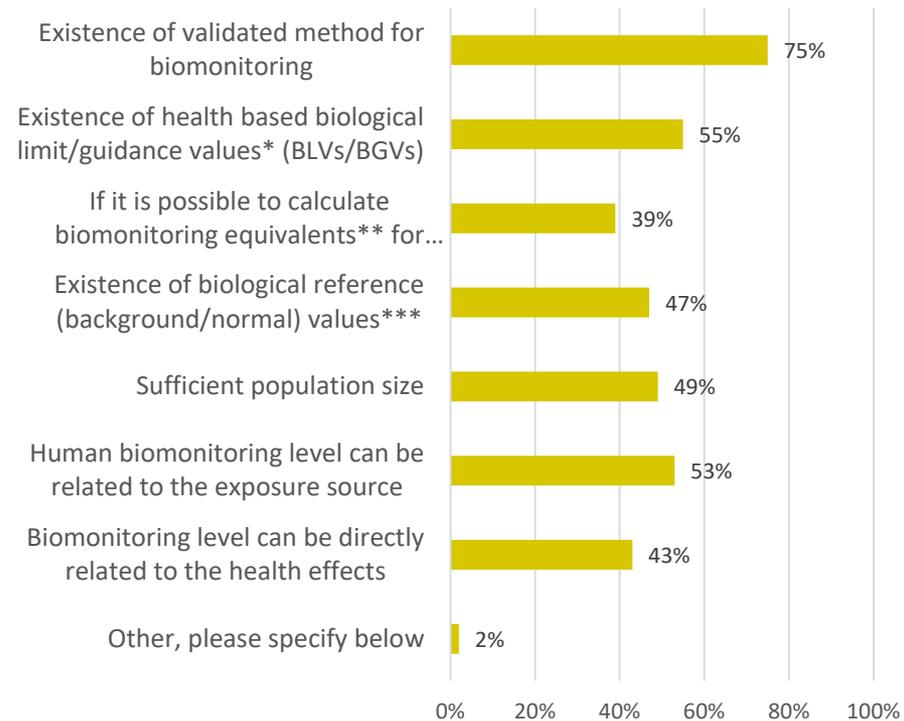


Biological limit/guidance values are needed to support the use of HBM

What are the criteria for using human biomonitoring data in risk assessment at workplaces?

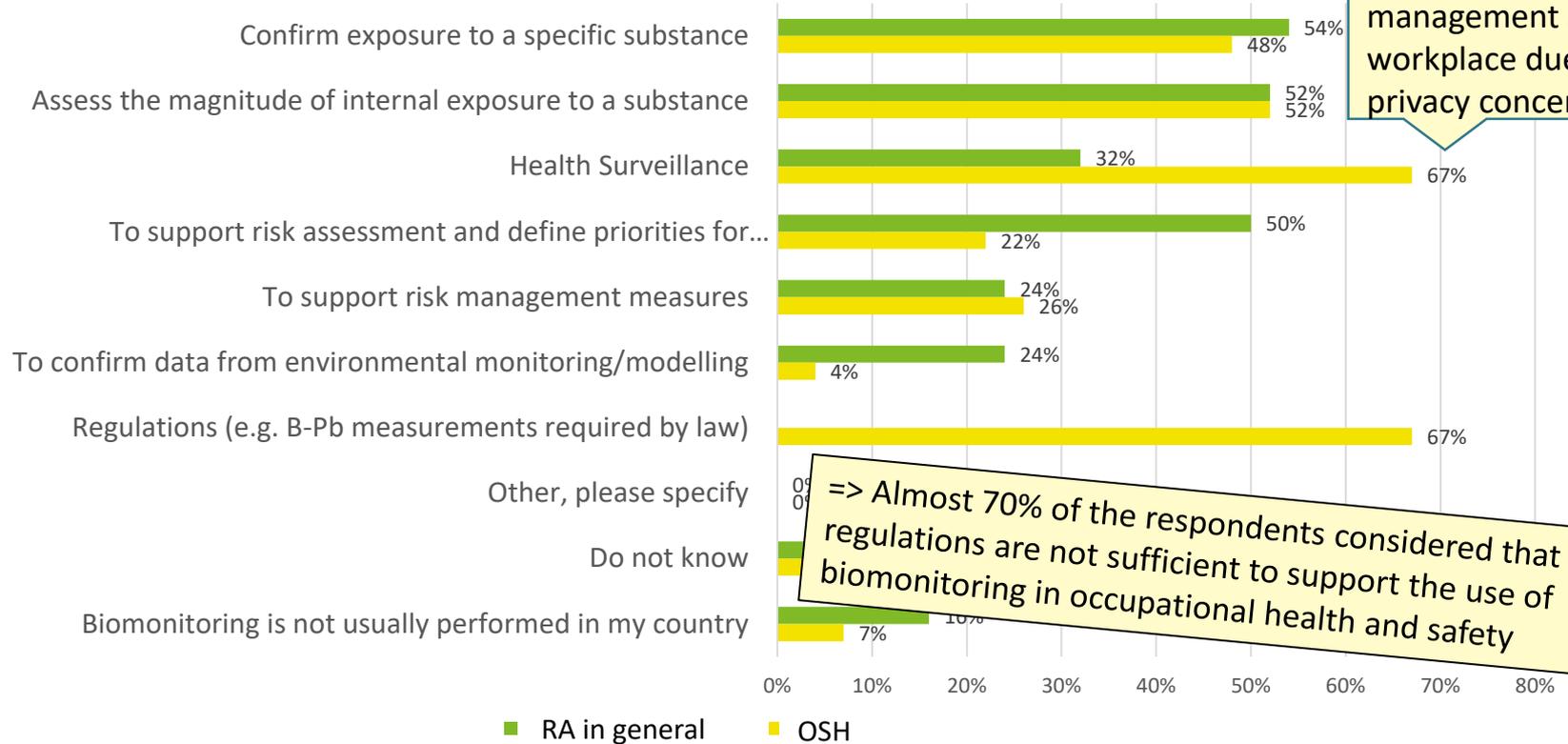


What are your criteria for using human biomonitoring data in risk assessment?



Health surveillance and regulations main drivers for biomonitoring in OSH, exposure assessment in RA in general

What are the main drivers to perform human biomonitoring?



Data, however, not necessarily used effectively for risk management at workplace due to privacy concerns.

=> Almost 70% of the respondents considered that regulations are not sufficient to support the use of biomonitoring in occupational health and safety

Main conclusions from the survey

- Need for better regulatory recognition of HBM
 - Inclusion of HBM and HBM limit values in legislation
- Need for supporting guidance for HBM use
- Need for guidance how to deal with ethical issues (including data protection)
- Need to clarify the role of HBM as a tool supporting workplace exposure assessment and risk management versus HBM as worker's health surveillance tool

Evaluation of RA schemes and examples

- Expert group consisting of participants from 16 EU institutions enrolled in HBM4EU, with expertise in chemical risk assessment, were asked to
 - Evaluate the current risk assessment schemes and identify whether the scheme includes a **guidance** on the **use of HBM** in RA, and if yes describe how this guidance takes HBM into account;
 - Identify whether HBM4EU priority substances have recently been evaluated under the scheme and if there are good examples on the use of HBM in regulatory risk assessment

Overview of risk assessment (RA) schemes

RA Scheme	HBM recognized as an exposure assessment tool	Biomarkers of effect recognized as possible tools for e.g. hazard characterization	Specific guidance available for the use of HBM in RA	Examples on the use of HBM exist? (given in brackets, if include HBM4EU priority chemicals)	Remarks
WHO	yes	yes	yes	Yes (toxic metals e.g. Hg/MethylHg, Cd, Cr), toluene, nitrobenzene, etc.)	GEMS; IPCS/INCHEM
FAO	yes	yes	no	no	
REACH	yes	no	+ / - *	Yes (phthalates, BPA, MOCA, chromates, MDA)	*REACH guidance R8 mentions the possibility to derive DNELs based on biomarker levels
EFSA	Yes	Yes	Yes	Yes (cadmium and lead)	Guideline for RA of contaminants in food and feed
EFSA review	Yes	Yes	No	Yes (Metals; PCBs; cotinine; mycotoxins; perchlorate; nitrosamine; alkaloids; dioxins; phthalates; PAHs; furans; fluorocarbons; organochlorines; phenols; PFCs; PBDEs; organophosphates; pyrethroids; chlorinated phenols; acrylamide; carbamates)	WHO RA guidance is followed
EFSA review	Yes	Yes	No	Yes (PCBs, PBDEs, PFASs, PAHs, Parabens, Perchlorate, BPA, Phytoestrogen, VOCs)	Document focused on vulnerable groups
EU Pesticides	yes	yes	no	HBM has been used for monitoring worker exposure. Most studied pesticides: Herbicides (in order): 2,4-D > atrazine > metolochlor = MCPA > alachlor = glyphosate. Insecticides (in order) were: chlorpyrifos > permethrin > cypermethrin = deltamethrin > malathion, Fungicides were: captan > mancozeb > folpet	Data from: HBM data collection from occupational exposure to pesticides –EFSA supporting publication 2017:EN-1185. 207 pp.
EU Biocides	yes	no	no	no	
EU Cosmetics	no	no	no	yes	HBM as support and complementary information only
EU OSH	yes	no (legislation, however, SCOEL methodology recognises this possibility)	no	only B–Pb taken into the legislation, however, SCOEL recommendations available for several priority chemicals	HBM as part of health surveillance. Under CAD or CMD no BLVs given except for P–Pb)
WHO- HIA	Yes	Not known	No	Yes (lead, dioxins, EDCs in general)	Current status: Dose-response relationships mainly based on external exposure

Examples on the use of occupational biomonitoring data in regulatory risk assessment

- 2,2'-dichloro-4,4'-methylenedianiline (MOCA) – application of authorization for the use of MOCA as a curing agent/chain extender in cast polyurethane elastomer production
 - Genotoxic carcinogen, BOELV of 0.01 mg/m³
 - Low vapour pressure, air levels often low (in many cases below LOD)
 - Skin exposure may significantly contribute to total exposure
 - Biomonitoring data available both from research studies and gathered by the industry
 - => shows exposure levels of 10 µmol/mol creatinine (90th percentile). This corresponds approximately the same dose as achieved by 8 h inhalation exposure to ~0.0035 mg/m³ (=35% of BOELV)

Gathering of aggregated HBM data available for use in occupational exposure assessment

Report of biomonitoring

Report of biomonitoring										
Measurement design								Measurement		
Particular tasks or conditions prior to sampling	Biological sample analysed	Timing of sampling	Biomarker analysed	Method of sample analysis	Limit Of Detection / Limit Of Quantification	Background level observed in general population	Number of measured data points / samples	Date of sampling	Measured value	Corrected or adjusted value
<i>tasks performed during the day of sample collection and, if relevant, also tasks in previous days; were circumstances normal during these days? (vs column B and D); e.g. mention if any unusual event occurred; or if there were any potential additional sources of exposure due to e.g. adjacent workplaces or smoking/implants/hobby etc.)</i>	<i>(e.g. urine spot sample, urine 24 hours, blood, exhaled air)</i>	<i>(e.g. day of the week, morning before starting work, in the end of the shift or both moments for the same worker)</i>	<i>(e.g. parent chemical or specific metabolite)</i>	<i>(reference to the official method used for sample preparation and detection of the biomarker)</i>		<i>(if known/available)</i>	<i>(for data-sets; ignore if reporting a single sample per row)</i>		<i>(value, unit, and analyte, e.g. 2µg Pb / 100ml blood) (value as measured, i.e. prior to any correction/adjustment or conversion; if known, possible also to include analytical error for a single measurement, e.g. ±0.01; for bigger data-sets, report min-max values and if relevant number of samples below LOD)</i>	<i>(if available; e.g. value corrected for creatinine or specific gravity, in case of urine sample; or value adjusted for lipid, in case of blood/serum sample)</i>

- https://echa.europa.eu/documents/10162/22979809/tmpl_reporting_occupational_exp_data_du_en.xlsx/84ef3203-4294-75c8-3b79-9c024abc2bcd

Other examples in which occupational biomonitoring data has been used in exposure and risk assessment

- Some other authorizations: MDA, some chromate authorisations, arsenic trioxide, trichloroethylene...
- Restrictions relevant for workers: bisphenol A restriction in thermal paper to protect cashiers (used to confirm exposure assessment, which was based on dermal exposure modelling)

Other biomonitoring initiatives (in addition to HBM4EU)

- OECD Working Party on Hazard Assessment (WPHA) and OECD Working Party on Exposure Assessment (WPEA) on Occupational biomonitoring and derivation of biomonitoring guidance or limit values
- ISES Europe Expert Working Group "Exposure Data Production: Human data"

Further reading

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Human biomonitoring in health risk assessment in Europe: Current practices and recommendations for the future



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Thank you

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