HBM4EU project

science and policy for a healthy future

HBM in occupational health – how HBM4EU aims to improve the use of HBM in occupational health

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1st HBM4EU Training School 2018

Aims of HBM4EU

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

Variable practices in different member states

Availability of biological limit values in different countries

Table 3-1: Number of BLVs used in each Member State

Member State	Number of BLVs		Source and date of latest information
	Binding/ Statutory	Recommendations/ guidance	
Austria	1 (lead)	None	Pers. comm. (questionnaire response)
Belgium	1 (lead)	None identified	Service public fédéral (SPF) Emploi, Travail et Concertation sociale (2002)
Bulgaria	1 (lead)	16	Ministry of Labour and Social Policy (MLSP) and Ministry of Health (MH) (2006)
Croatia	1 (lead)	50	Ministry of Economy, Labour and Entrepreneurship (2009)
Cyprus	1 (lead)	None identified	Ministry of Labour, Welfare and Social Insurance (2001)
Czech Republic	1 (lead)	6	Pers. comm. (national expert)
Denmark	1 (lead)	None	Pers. comm. (questionnaire response)
Estonia	1 (lead)	None	Riigi Teataja (2000)
Finland	1 (lead)	16	Kiilunen (2013); Kiilunen (2015); pers. comm. (questionnaire response)
France	1 (lead)	2	Institut National de Recherche et Sécurité - INRS (2016); ANSES (2011)
Germany	1 (lead)	66	BAuA (2015)
Greece	1 (lead)	None identified	Greek Institute for health and Safety at Work (2001)
Hungary	1 (lead)	Based on ACGIH with 19 chemical agents included	Anon (2000)
Ireland	1 (lead)	51	ISB (2000); Health and Safety Authority HSA (2011)

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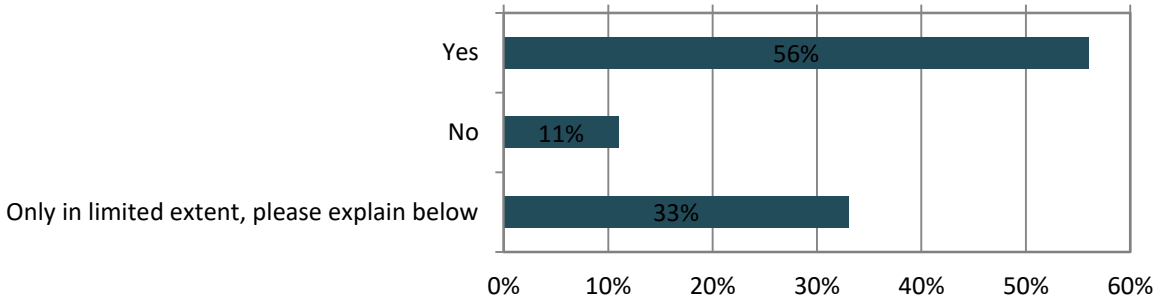
Italy	1 (lead)	All chemical agents for which limits have been set by ACGIH, DFG (Germany)	SPSAL Della Provincia di Modena (nd)
Latvia	11 (including lead)	None	Pers. comm. (questionnaire response)
Lithuania	1 (lead)	None identified	Minister of Social Security and Labour and Minister of Health (2001)
Luxembourg	1 (lead)	None identified	Anon (2002)
Malta	1 (lead)	None	Occupational Health and Safety Authority (2012); pers. comm. (questionnaire response)
Netherlands	1 (lead)	None identified	EASHW (2007)
Poland	1 (lead)	37	ILO (2002), Pers. comm. (questionnaire response)
Portugal	1 (lead)	None identified	Binks (2013)
Romania	52 (including lead)	None	Government of Romania (2015)
Slovakia	1 (lead)	9	EASHW (2007)
Slovenia	49 (including lead)	None	Pers. comm. (questionnaire response); PIS (2002)
Spain	1 (lead)	45	Instituto Nacional de Seguridad e Higiene en el Trabajo - INSHT (2016)
Sweden	2 (lead, cadmium)	None identified	Swedish Work Environment Authority (2005; 2015)
UK	1 (lead)	14 BMGVs non-statutory	HSE (2011)

Ref. RPA, 2017: Second study to collect updated information for a limited number of chemical agents with a view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

Survey made under WP5.3 to national experts

- Aim: to gather information from national regulatory risk assessors on their risk assessment practices, the use of human biomonitoring, and the criteria or possible obstacles related to its use.

3B. Is human biomonitoring regularly applied in your country in occupational safety and health?



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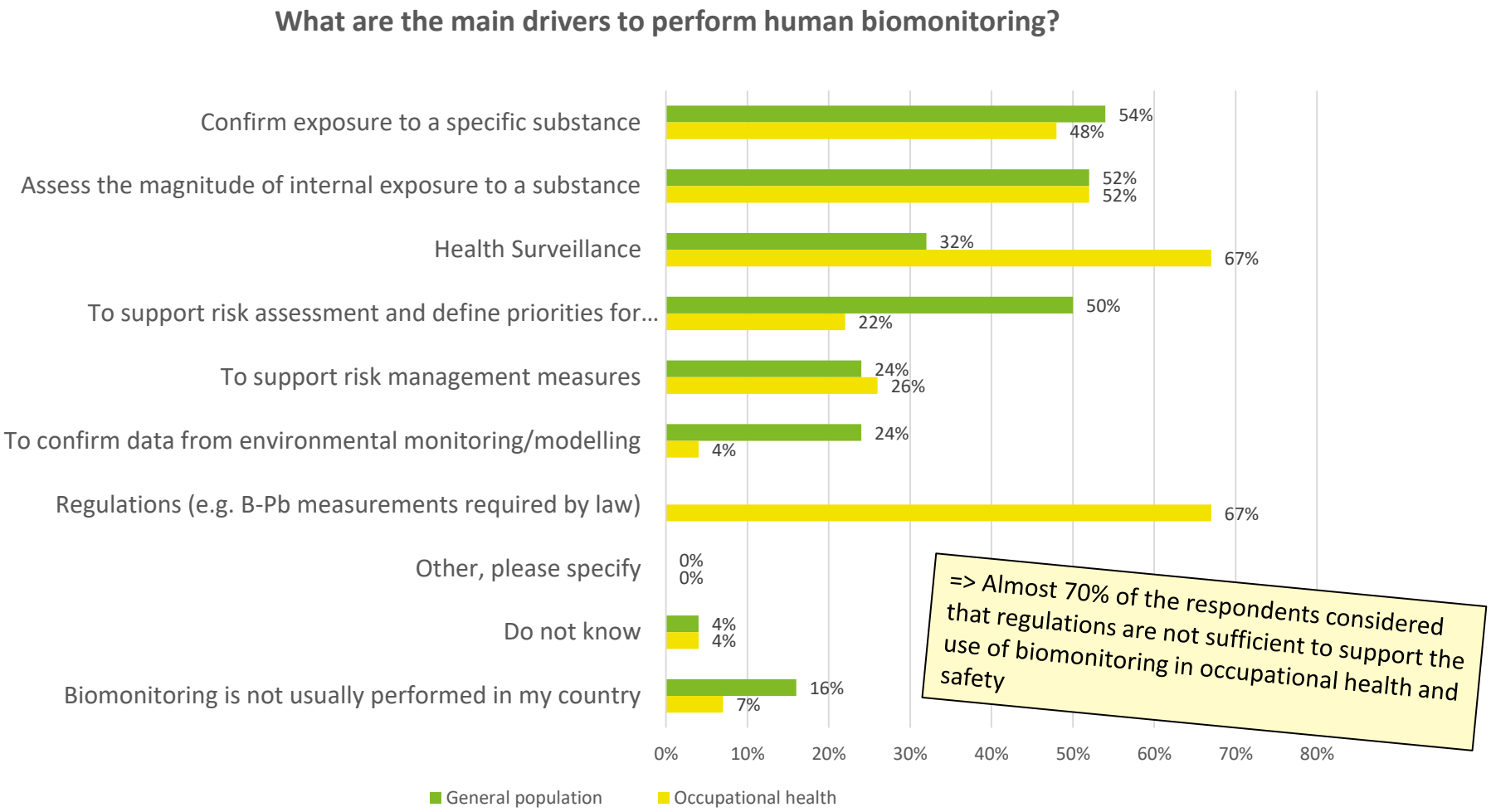
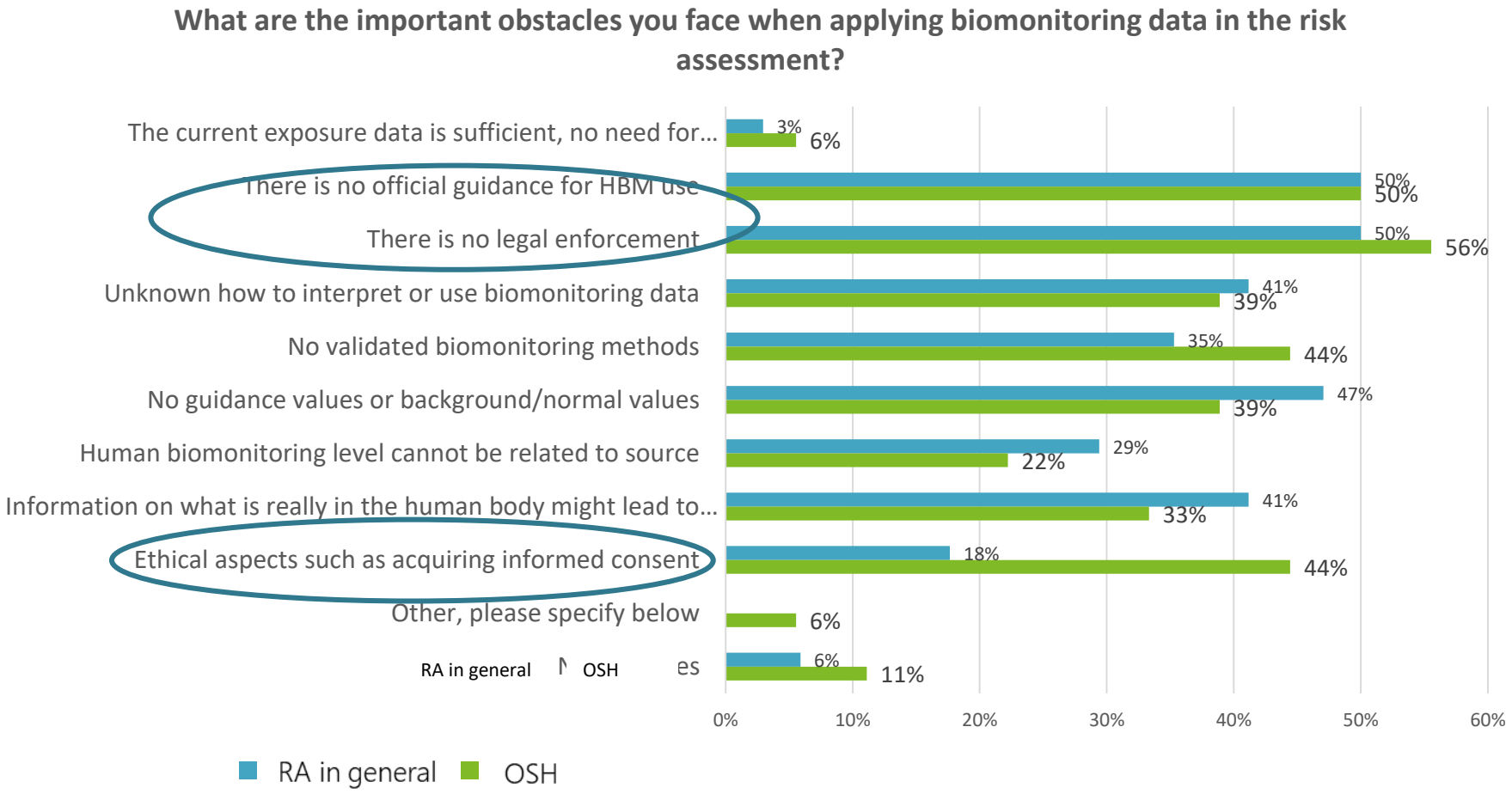
Health surveillance and regulations main drivers for biomonitoring in OSH



Need for the development of the guidance and supporting legislation



EU legislation

Overall, it seems that CAD/CMD needs updating in order to include more BLVs.

- Chemical Agents directive (98/24/EC)
  - Possibility to give binding biological limit values (like B-Pb)
  - No indicative biological limit values
- Carcinogens and Mutagens directive (2004/37/EC)
  - Not possible to give any biological limit values?
    - Currently discussed in the case of Cd
- Scientific Committee on Occupational Exposure Limit values (SCOEL) has, however, recommended biological limit or guidance values for >20 different substances

Opinion of the Advisory Committee on Safety and Health at Work (2017) on inclusion of biological limit values in CMD

- Recognizes that biomonitoring could provide useful information in some situations
- Notes that in Annex II to CMD, a recommendation is set out for the health surveillance to include where appropriate, biological surveillance, as well as the detection of early and reversible effects
  - Recommends to add a reference to SCOEL limit values
- Does not support the amendment of CMD by incl
  biomonitoring or biological limit or guidance valu
  recommended by SCOEL.
- Instead, recommends to develop EU level guidance on biological monitoring for both carcinogens and mutagens as well as other hazardous substances falling under CAD

How could HBM4EU support this?

Biomonitoring and EU Chemicals Legislation (REACH)

- Under REACH it is (in principal) possible to set DNELs for biomarkers
- In REACH restriction and authorization processes, biomonitoring data could be really useful in decision making and have been increasingly applied recently
- E.g. authorizations: HBM data almost systematically asked if the substance has biomonitoring method
  - Sometimes challenges with privacy claims of "health data"
- Several authorization permissions in which biomonitoring has been included as one of the conditions of the authorization

Example on the additional conditions for authorization of TCE (www.echa.Europa.eu)

Description for additional conditions and monitoring arrangements:

The applicant must implement regular campaigns of occupational exposure measurements (sampling at least annually) relating to the use of TCE described in this application. These monitoring campaigns must be based on relevant standard methodologies or protocols and comprise both personal inhalation exposure sampling and biomonitoring (measurement of the TCE metabolite TCA in urine), be representative of the range of tasks undertaken where exposure to TCE is possible and of the total number of workers that are potentially exposed (i.e. the campaign shall include process, maintenance and laboratory workers). The results of the monitoring must be included in any subsequent authorisation review report submitted.

HBM4EU priority chemicals and current EU policy interests for occupational data

CMD

Chromium: EU BOELV, high when considering the health risks, how achievable are the lower levels?

B[a]B and PAHs: included but no limit value given, exposure levels, BOELV in future?

Cadmium: BOELV under consideration, BLV?

Anilines: BOELV for MOCA, BLV not considered, relevance questionable due to authorization

Acrylamide: EU BOELV

Arsenic: EU BOELV under consideration

CAD: Lead ?

REACH

Chromium(VI) authorized, need for representative EU-wide data, including biomonitoring data

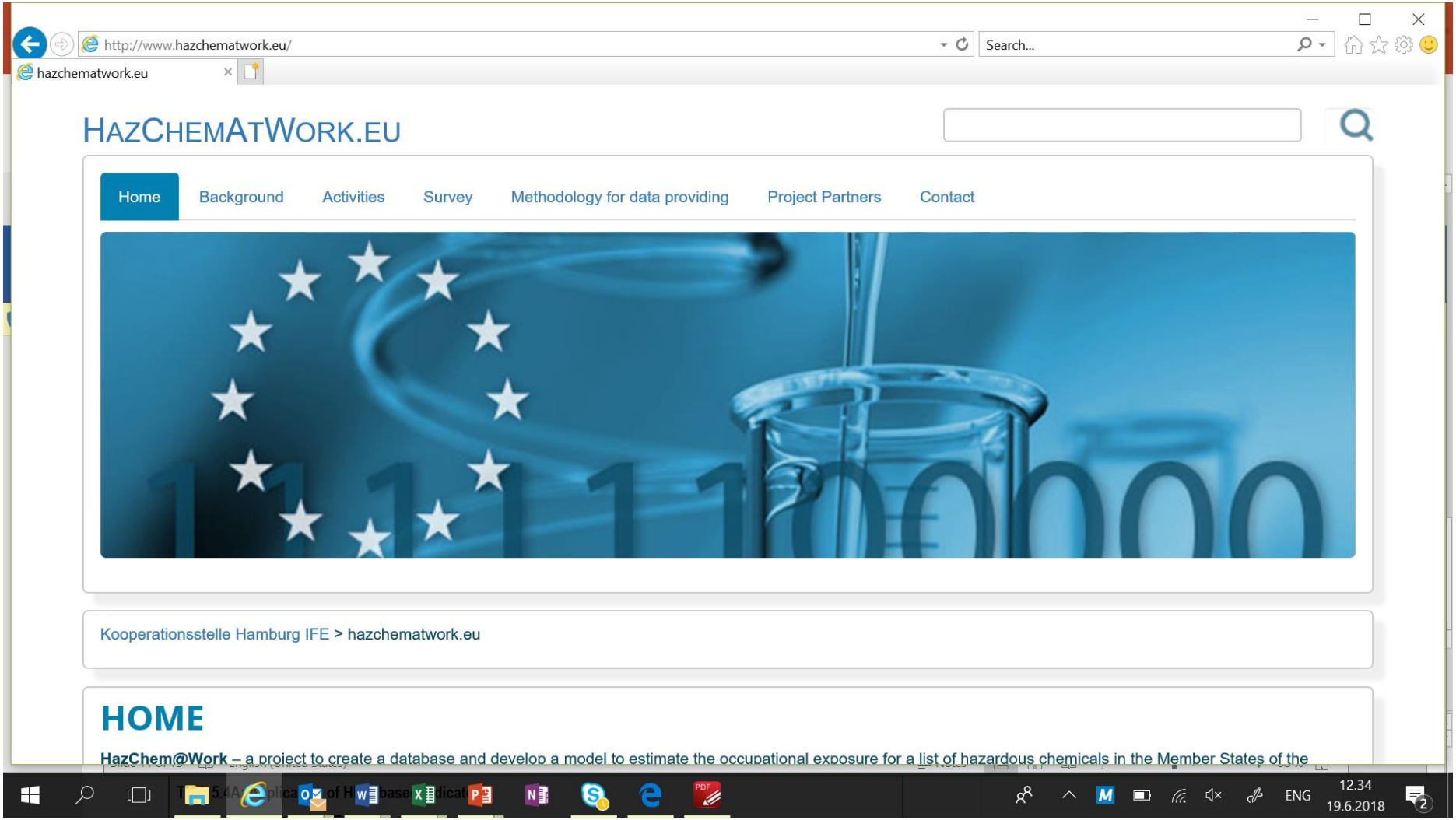
PAHs: coal tar pitch/antracene oil authorized

Diisocyanates restriction for occupational use currently waiting for Commission decision: when coming in force needs follow-up and good methods for exposure identification

Bisphenol A restriction in thermal papers

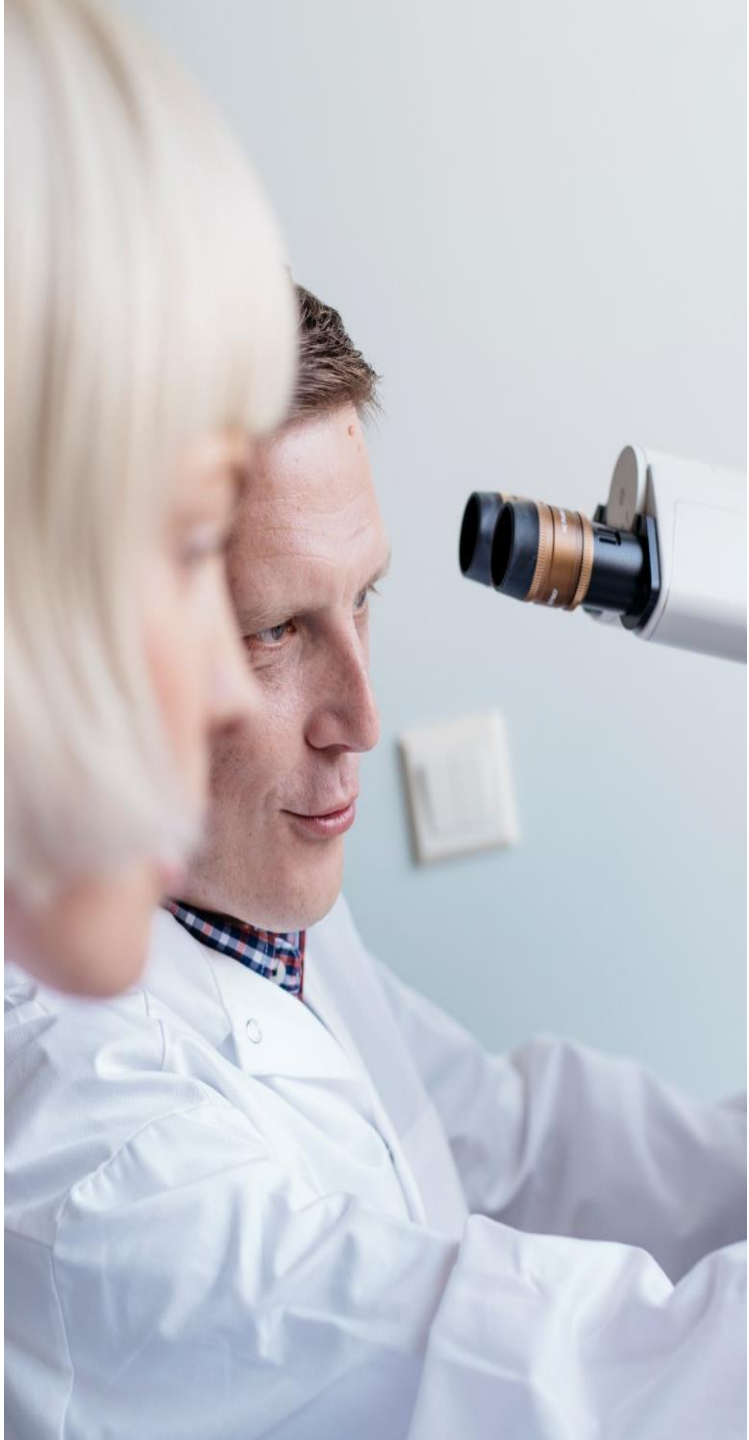
Aprotic solvents: NMP – restriction (DMF will follow)

Occupational Exposure Databases



How can HBM4EU improve the use of biomonitoring in occupational health?

- EU-wide data useful for both REACH and OSH
- New methods
- Examples to demonstrate the usefulness of HBM
- Good practices to use the HBM data together with air monitoring data in exposure assessment
- =>Strengthen the role of exposure biomonitoring as a tool for exposure assessment
- => Increase the acceptability of biomonitoring across the Europe and better inclusion of HBM in EU legislation
- …….



Contacts

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Speaker's information

Tiina Santonen, MD, PhD, MSc in Applied Toxicology, works as Chief Specialist at Finnish Institute of Occupational Health. Her main tasks at the institute relate to chemical risk assessment and biomonitoring. She is the member of Scientific Committee on Occupational Exposure limits (SCOEL) and ECHA Risk Assessment Committee (RAC). In HBM4EU she is responsible for tasks 5.3 related to the better use of HBM in the risk assessment of chemicals and task 8.5 related to targeted occupational surveys.

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