Group 3 National Hub Template (HBM data for policy development)

Group Leader: Hans Reynders and Karen Van Campenhout

(hans.reynders@vlaanderen.be, karen.vancampenhout@vlaanderen.be)

DOMG

Name and email of National Hub Author: Petra Apel (UBA), petra.apel@uba.de and Marike Kolossa (UBA), marike.kolossa@uba.de

Narrative estimation: 2-3 pages

Introduction:	
Background information on the evolution and status of your National HBM programme in your country. Include year of establishment - Who pays for the programme of work? Give web links.	Health related environmental monitoring and human biomonitoring studies at the federal level in Germany lay in the responsibility of the German Environment Agency (UBA) and the Ministry for the Environment, Nature Protection and Nuclear Safety (BMU). The main instruments were established in the early 1980s and are used since then continuously (Schulz et al., 2007). The German HBM system consists of different components (Kolossa et al., 2012) that, complementing each other, enable a comprehensive assessment of human exposure to chemicals, provide indications of sources of exposure and help monitor the effectiveness of regulatory measures. The main pillars are a) the cross-sectional population-representative German Environmental Surveys (GerES) combining health and HBM surveillance as well as additional environmental monitoring, b) the Environmental Specimen Bank (ESB) as a specific instrument for time-trend analyses, c) in a co-operation between the BMU and the German Chemical Industry Association (VCI) the development of new analytical methods for the monitoring of substances to which the general population might be exposed and/ or which are of health relevance (Kolossa et al., 2017), d) the provision of assessment tools by the German Human Biomonitoring (HBM) Commission. The German HBM Commission serves since its founding more than 20 years ago as the German National Hub in the field of Human Biomonitoring. It consists of experts from different fields, representatives from the scientific higher federal authorities responsible for chemical risk assessment, management, health surveillance, and observers from the ministerial level. It has been providing expert advice to the Federal Environment Agency on all issues relevant for human biomonitoring studies, be it study design, analytics or the evaluation of collected data. Since 1996, the Commission has published statements on fundamental and practical issues of human biomonitoring, predominantly in German to facilitate access by public health services and state authorities. In HBM4EU, the many years of experience in the field of HBM could be shared at European level. At the same time, the mutual transfer of knowledge and data within the framework of HBM4EU enabled a critical examination of different methods and approaches to

	improve and harmonise study implementation and evaluation in Europe. With the inclusion of the research institutions taking part as linked third parties in HBM4EU the National Hub was extended and further developed, and a further connection between HBM4EU and national activities created.
Main text - Results and Discussion ENSURE YOUR NARRATIVES ARE REFERENCED AS FAR AS POSSIBLE	
• Describe which ministries (Environment, Health etc.)/policy makers and stakeholders involved/steering/financing the HBM programme. • Involvement with HBM and Steps/processes used in involving policy makers. • Is HBM included in their business/strategic/action plan. • State which ministry is HBM data reported to or it is being utilized.	The HBM Commission is interdisciplinary (i.a. chemists, toxicologists, physicians, statisticians, epidemiologists). The members are scientists from federal and state authorities, universities, hygiene institutes and clinics who are appointed by the President of the Federal Environment Agency on the basis of their expertise for three years at a time. Reappointment is possible. Membership of the Commission is honorary. The members receive attendance allowances and travel expenses in accordance with the applicable federal regulations. In addition to the members, representatives of the Working Group of the Supreme State Health Authorities, the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety, the Federal Ministry of Health, the Robert Koch Institute, the Federal Institute for Risk Assessment and the Federal Environment Agency are involved in the work of the HBM Commission as permanent guests, so that a transfer of information between different departments and the federal and state levels is ensured. Furthermore, experts on selected topics are sometimes called in as advisory guests (https://www.umweltbundesamt.de/en/topics/health/commissions-working-groups/human-biomonitoring-commission-hbm-commission). Linked third parties are 1. the Institute for Prevention and Occupational Medicine of the German Social Accident Insurance (IPA), 2. the Institute and Outpatient Clinic of Occupational, Social and Environmental Medicine of University Erlangen (IPASUM), 3. the Fraunhofer Institute for Biomedical Engineering (IBMT), 4. the Helmholtz Centre for Environmental Research (UFZ Leipzig) and 5. the Federal Institute for Risk Assessment (BfR).
• Describe barriers e.g funding; challenges e.g. participant recruitment; opportunities e.g. enhancing cross government working and linking of env data with exposure measurements currently at play in your country with regards to HBM or other things of note. • Have any of these barriers been addressed by HBM4EU? If yes - describe.	*Not applicable, as the German National Hub does not conduct the population representative and time trend studies itself (UBA is responsible (see above), owner of the data and funded by the BMU). The only point may be that unpaid experts have limited time to prepare discussion documents and that this preparation needs to be done and financed by UBA.*

• Elaborate on issues which propelled the establishment and sustainability of your HBM programme.	The German National Hub does not conduct the German population -representative and time trend studies itself, but the HBM Commission was involved in the prioritisation of substances to be investigated under GerES V (Schulz et al., 2017) and later also in the prioritisation of substances to be investigated under HBM4EU. This latter ensured that knowledge gaps known from municipal and Federal States authorities and public health services were included and addressed in the HBM4EU process. An essential task of the HBM Commission is to establish assessment values (reference and HBM values) for selected substances according to defined criteria. These values serve to provide a comprehensible and uniform assessment of HBM results, whether they are representative from the German Environmental Surveys or whether they are from time-trend analyses, or are collected on an occasion-related basis at the level of the Federal States. The reference values are derived by means of statistical methods and describe the basic exposure of the population. Measured values that are higher than the reference values are an indication of increased exposure compared to the general population, but are not apt to interpret health risks (Angerer et al., 2011; Apel et al., 2017). In the HBM4EU context, a scientific exchange took place between HBM4EU staff and members of the HBM Commission on derivation options and methods for reference values, which was also reflected in a corresponding publication (Vogel et al., 2019). Conversely, the HBM Commission itself initiated a revision and specification of the reference value concept at national level. The assessment values relevant for a health risk assessment are the HBM-I and -II values, which are toxicologically and/ or epidemiologically derived. The HBM-I value is defined as the concentration of a substance in human biological material (e.g. urine, blood, hair) at and below which no risk of adverse health effects is to be expected and consequently there is no need for action. The HBM-II value represents an intervention level, where an increased risk for adverse health effects is assumed (HBM Commission, 1996; HBM Commission, 2007; Angerer et al., 2011; Apel et al., 2017). Building on this concept as well as the concept of BE values (Hays et al., 2007; 2008; Aylward et al., 2013) and the work of ANSES (2014) on guidance in the occupational field, the strategy to derive HBM-GV under HBM4EU was developed (Apel et al., 2020). HBM-GVs for the general population are equivalent to HBM-I values but go through a broad and Europe wide consultation process mediated via National Hubs before finalisation. For the derivation of some values, preparatory work by the HBM Commission was available. Conversely, the Commission members have the opportunity to comment on the respective HBM4EU substance dossiers. The HBM Commission is currently examining the extent to which it can adopt the HBM-GVs which are based on a current literature search and are agreed on under HBM4EU. Furthermore, the evaluation of chemical mixtures with regard to health risk has been on the agenda of the HBM Commission for a

	long time as far as phthalates are concerned, and there has been mutual impulses for a continuation of the work in the HBM Commission and in the HM4EU project. Additionally, HBM4EU gave input for modifying the German HBM activities to facilitate comparability of study conduct and results with data and the standards developed by HBM4EU.
• Detailed information of HBM priority substance used for policy development e.g. disaster, pollution, incidence/prevalence of a health-related issue. • Give examples where the work has led to policy implementation, monitoring, or control of chemical exposures etc • Have HBM or other monitoring activities been linked or adapted. Give examples in detail.	The assessment values mentioned above, together with additional information, help in an assessment of findings on which all participants in the representative German studies receive feedback. However, the assessment values are even more essential for the interpretation of the measured HBM data in relation to the health risk for the population and can serve policy makers as a basis for possible risk management measures (Choi et al., 2015). Since the German Human Biomonitoring System is financed with funds from the Environmental Research Plan and UBA is responsible for its proper implementation, UBA reports regularly data and recommendations to the BMU so that the Ministry of the Environment can take legislative (regulatory) action on the basis of this scientific information if necessary. In addition, other ministries, federal and state authorities are informed via the HBM Commission so that they can act accordingly. For example, the provision of HBM-I and -II values for PFOA and PFOS was helpful for the Federal States to initiate and control minimisation measures. Additionally, they supported the initiative to propose a ban for the whole substance group. Parliamentarians were also informed at their request.
• Other players who would be beneficial in the continued support of HBM at a governmental level and working together to promote HBM in your country. • Have you used HBM4EU data e.g newsletter, videos to support policy?	Thus, the German system as a longstanding and well-established tool has proven itself at the national level and is also increasingly benefiting from the international activities and networks, as the many open questions can be solved more quickly and precisely by a large number of actors. For example, the Europe-wide quality assurance of analytical methods and laboratories driven by the linked third parties as well as the harmonized SOPs for study preparation, sampling and storage of human samples, the knowledge gain regarding adverse outcome pathways and nontarget screening do not only provide valuable results for the HBM4EU project but will also be important for the further work of the German National Hub, including the HBM Commission and the UBA. The monthly newsletter 'HBM4EU Science Digest', is particularly appreciated for a quick overview of specialist topics. HBM4EU results and conclusions are continuously used to inform general population, stakeholder and other players concerned via the UBA website, social media and other communication products.
Future Plans	
• Ways/process used in maintaining the programme • What are your future plans? • Do you think PARC will be crucial to the sustainability of your HBM programme?	In the future, environmental and human biomonitoring will increasingly be better linked in order to come closer to the overarching goals of the European Commission (zero pollution ambition). PARC will offer the opportunity to sustain the achievements of HBM4EU, sustain and further develop environmental and human monitoring, the respective tools and methodologies and establish thus a continuous support for science based policy making.

Literature	Angerer J, Aylward LL, Hays SM, Heinzow B, Wilhelm M (2011). Human biomonitoring assessment values: approaches and data requirements. Int. J. Hyg Environ. Health 214 (5), 348–360. https://doi.org/10.1016/j.ijheh.2011.06.002. ANSES (2014). Reference Document for the derivation and the measurement of exposure limit values for chemical agents in the workplace (OELs). French Agency for Food Environ. Occupat. Health. Safety (ANSES). https://www.anses.fr/en/system/files/VLEP2009sa0339RaEN.pdf Aylward LL, Kirman CR, Schoeny R, Portier CJ, Hays SM (2013). Evaluation of biomonitoring data from the CDC National Exposure Report in a risk assessment context: perspectives across chemicals. Environ. Health Perspect., 121 (3) (2013), pp. 287-294. Apel P, Angerer J, Wilhelm M, Kolossa-Gehring M (2017). New HBM values for emerging substances, inventory of reference and HBM values in force, and working principles of the German Human Biomonitoring Commission. Int. J. Hyg Environ. Health 220 (2 Pt A), 152–166. https://doi.org/10.1016/j.ijheh.2016.09.007. Apel P, Rousselle C, Lange R, Sissoko F, Kolossa-Gehring M, Ougier E (2020). Human biomonitoring initiative (HBM4EU) - strategy to derive human biomonitoring guidance values (HBM-GVs) for health risk assessment. Int. J. Hyg Environ. Health, 230, p. 113622, 10.1016/j.ijheh.2020.113622. Choi J, Mørck TA, Polcher A, Knudsen LE, Joas A (2015). Review of the State of the Art of Human Biomonitoring for Chemical Substances and its Application to Human Exposure Assessment for Food Safety. EFSA supporting publication, 2015: EN-724. Hays SM, Becker RA, Leung HW, Aylward LL, Pyatt DW (2007). Biomonitoring equivalents: a screening approach for interpreting biomonitoring results from a public health risk perspective. Regul. Toxicol. Pharmacol., 47 (1), pp. 96-109. Hays SM, Aylward LL, LaKind JS, Bartels MJ, Barton HA, Boogaard PJ, Brunk C, DiZio S, Dourson M, Goldstein DA, Lipscomb J, Kilpatrick ME, Krewski D, Krishnan K, Nordberg M, Okino M, Tan YM, Viau C, Yager JW (2008). Guidelines for the derivation of biomonitoring equivalents: report from the biomonitoring equivalents expert workshop. Regul. Toxicol. Pharmacol., 51 (3 Suppl. l), pp. 4-15. HBM Commission (1996). HBM-Kommission des Umweltbundesamtes: Konzept der Referenz- und Human-

Biomonitoring-Werte (HBM) in der Umweltmedizin. Bundesgesundheitsbl, 39 (6) (1996), pp. 221-224.

HBM Commission (2007). HBM-Kommission des Umweltbundesamtes: Ableitung von Human-Biomonitoring-(HBM) Werten auf der Basis tolerabler Aufnahmemengen - Teil II: Grundlagen und Ableitungsweg. Bundesgesundheitsbl, 50 (2), pp. 251-254.

Kolossa-Gehring M, Becker K, Conrad A, Schröter-Kermani C, Schulz C, Seiwert M (2012). Environmental surveys, specimen bank and health related environmental monitoring in Germany. Int. J. Hyg Environ. Health 215 (2), 120–126. https://doi.org/10.1016/j.ijheh.2011.10.013.

Kolossa-Gehring M, Fiddicke U, Leng G, Angerer A, Wolz B (2017). New human biomonitoring methods for chemicals of concern—the German approach to enhance relevance. Int. J. Hyg. Environ. Health, Volume 220, Issue 2, Part A, pp 103-112. http://dx.doi.org/10.1016/j.ijheh.2016.10.012.

Schulz C, Conrad A, Becker K, Kolossa-Gehring M, Seiwert M, Seifert B (2007). Twenty years of the German environmental survey (GerES): human biomonitoring – temporal and spatial (West Germany/East Germany) differences in population exposure. Int. J. Hyg. Environ. Health, 210 (3–4), pp. 271-297.

Schulz C, Kolossa-Gehring M, Gies A (2017). German environmental survey for children and adolescents 2014-2017 (GerES V)–the environmental module of KiGGS wave 2. Journal of Health Monitoring 2 (S3), 45–51. https://doi.org/10.17886/RKIGBE-2017-108.

Vogel N, Conrad A, Apel P, Rucic E, Kolossa-Gehring M (2019). Human biomonitoring reference values: Differences and similarities between approaches for identifying unusually high exposure of pollutants in humans. International Journal of Hygiene and Environmental Health,
Volume 222, Issue 1 pp 30-33.
https://doi.org/10.1016/j.ijheh.2018.08.002.