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# Policy recommendations and cost implications for a more sustainable framework for European human biomonitoring surveys

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#### ABSTRACT

The potential of Human Biomonitoring (HBM) in exposure characterisation and risk assessment is well established in the scientific HBM community and regulatory arena by many publications. The European Environment and Health Strategy as well as the Environment and Health Action Plan 2004-2010 of the European Commission recognised the value of HBM and the relevance and importance of coordination of HBM programmes in Europe. Based on existing and planned HBM projects and programmes of work and capabilities in Europe the Seventh Framework Programme (FP 7) funded COPHES (COnsortium to Perform Human Biomonitoring on a European Scale) to advance and improve comparability of HBM data across Europe. The pilot study protocol was tested in 17 European countries in the DEMOCOPHES feasibility study (DEMOnstration of a study to COordinate and Perform Human biomonitoring on a European Scale) cofunded (50%) under the LIFE + programme of the European Commission. The potential of HBM in supporting and evaluating policy making (including e.g. REACH) and in awareness raising on environmental health, should significantly advance the process towards a fully operational, continuous, sustainable and scientifically based EU HBM programme. From a number of stakeholder activities during the past 10 years and the national engagement, a framework for sustainable HBM structure in Europe is recommended involving national institutions within environment, health and food as well as European institutions such as ECHA, EEA, and EFSA. An economic frame with shared cost implications for national and European institutions is suggested benefitting from the capacity building set up by COPHES/DE-MOCOPHES.

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#### 1. Introduction

Increasing public environmental health interest and awareness has developed over the past 20 years from concerns of the (general) public, regulators, and non-governmental organisations (NGOs) about rising incidence rates for a number of important diseases, and the potential risks of exposure to environmental stressors (e.g. endocrine disruptors) for human reproduction and health. As a consequence a better understanding of the health and environment relationships is asked for, and requests for collective as well as individual data on exposure that could be used for risk assessment and management are constantly growing.

To reduce potential risks a considerable number of regulatory measures has been taken on EU level in particular for chemicals, which requires health risk assessment for workers and the general population. A better understanding of determinants of health is also required to improve effective health promotion and disease preventive policies and to reduce public health costs.

Human biomonitoring (HBM) surveys can be used to establish baseline levels of chemicals in the investigated population, to compare exposures and to help identify priority chemicals for which further action should be taken. An important field is use of HBM in policy surveillance, identification of new risks, and benefits for risk assessment and chemicals regulation (Kolossa-Gehring, 2012).

HBM is a growing discipline used for exposure and risk assessment in environmental and occupational health (Manno et al., 2010; Angerer, 2012; Knudsen and Merlo, 2012). In environmental health, a number of studies have been performed with newborns (Casas et al., 2013; Leventakou et al., 2014; Pedersen et al., 2013; Papadopoulou et al., 2013)), children (Frederiksen et al., 2014; Mørck et al., 2014a; Conrad et al., 2010), and adults with classical biomarkers of exposure (Bevan et al., 2013; De Felip et al., 2014) as well as promising markers of effect (Stayner et al., 2014; Pedersen et al., 2013; Merlo et al., 2014; Silins and Hogberg, 2011) and new 'omics' techniques (Knudsen and Merlo, 2012; Hebels et al., 2013; Vrijheid et al., 2014; Kyrtopoulos, 2013; Vineis et al., 2013).

Several EU financed projects have developed and validated human biomarkers such as the PHIME (Public Health Impact of long-term, low-level Mixed element Exposure in susceptible population strata) integrated project, Newgeneris (Newborns and Genotoxic exposure risks: Development and application of biomarkers of dietary exposure to genotoxic and immunotoxic chemicals and of biomarkers of early effects, using mother-child birth cohorts and biobanks) programme (Merlo et al., 2009), or the ECNIS (Environmental Cancer Risk, Nutrition and Individual Susceptibility) network of excellence or OBELIX (Obesogenic endocrine disrupting chemicals: linking prenatal exposure to the development of obesity later in life).

HBM activities in Canada, France, Belgium (Flanders), Germany, India, and Romania have been described in the textbook issued in 2011 (Knudsen and Merlo, 2012) when activities were also known in countries as Austria (Hohenblum et al., 2012), Czech Republic (Cerná et al., 2012), Poland (Jakubowski and Trzcinka-Ochocka, 2005), Sweden (Bergkvist et al., 2010), and US (CDC, 2010).

HBM data can be used to determine whether the level of exposure of the public, special subgroups or individuals are acceptable or whether measures need to be taken. HBM can be used to monitor whether bans on substances or restrictions on their use have led to a decrease in exposure, and HBM can provide information on substance properties and potential risks.

But European countries differ largely in their priority setting, environmental concerns, registration governance, culture and ethics, as well as in their resources in terms of budget, manpower and expertise and there is a severe lack of comparable data and coherent approach within the European Union. Fragmentation between countries and studies however, strongly limits the use of results for European health impact assessments and cross-border comparison as well as the evaluation of key European chemicals, and customers policies. To allow a better use of the data and to evaluations at European scale and international scale, harmonisation of activities has been considered to be required urgently (Joas et al., 2012).

Therefore in 2003 the European Commission and the European Member States (MS) started efforts to construct an efficient HBM framework across the European Union within the European Environment & Health Strategy (SCALE) and in particular the Environment and Health Action Plan for Europe (EHAPE 2004–2010). As a result a preparatory feasibility study (ESBIO) was conducted from 2005–2007 (Viso et al., 2009; Joas et al., 2012) that discussed

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