HBM4EU science and policy for a healthy future

HORIZON2020 Programme
Contract No. 733032 HBM4EU

Public consultation on behalf of the Commission on: "The benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting properties"

- Comments from HBM4EU -

1 General comment

As representative of HBM4EU we fully support the presented guidelines on the benefit-risk analysis of phthalates with CMR properties in medical devices. These guidelines strengthen the need for assessing the benefit of these phthalates in medical devices by weighing the evidence of using alternatives against the benefit of using CMR phthalates. Because of the high concern among the HBM4EU partners as well as the EU and national policy makers, phthalates were selected as one of the first prioritised substance groups in HBM4EU and decided to investigate the aggregate exposure of people in Europe from all sources and describe the background exposure levels. As of 2019, human samples will be collected in different European countries in which the exposure to phthalates and the other priority substances will be measured. Human biomonitoring data from the European DEMOCOPHES study that included 17 countries showed already widespread exposure to phthalates in European citizens in 2011 when samples were taken (Den Hond et al. 2015). Recent human biomonitoring data from single European countries, e.g. collected within the 'German Environment Survey' (GerES V 2014-2017, paper in preparation) indicate that despite existing regulations, populations are still exposed to these phthalates. In addition, several studies showed an age-difference in exposure with children having in general higher exposure levels. As DEHP is used in the majority of medical devices, children, neonates and pre-term babies undergoing repeated medical treatment, especially in intensive care units are at risk for higher exposure levels of DEHP (and other CMR phthalates). But also unborns can be exposed to high levels of CMR phthalates if the pregnant women undergoing intensive medical treatment. As the critical effects of those phthalates are on the development, especially on male reproductive development, the higher exposure through medical treatment can result in higher risks for developing adverse health effects. For that reason, it should be special attention laid on the use of alternatives in medical devices and even go beyond and ban the use of CMR phthalates in medical devices as already done in consumer products. In France, there is already a ban for DEHP in tubes used in paediatrics, neonatology and maternity wards in hospitals from 2015. Even though, often argued that DEHP show unique stabilising properties which increases the viability of red blood cells in blood bags and/or containers, recent studies showed promising DEHP-alternatives for such uses, such as DINCH (Morishita et al., 2017). If benefit-risk analysis comes to the conclusion that CMR phthalates must be used, biomonitoring, especially of the high risk subpopulation should be warranted.

2 Attachment (additional non-confidential information) to comments

The European Human Biomonitoring Initiative (HBM4EU) is a joint effort of 112 partners from 28 countries, the European Environment Agency and the European Commission, co-funded under Horizon 2020 and running from 2017 to 2021. The aim is to develop a harmonized approach for the collection of human biomonitoring (HBM) data in the participating countries and to generate an aligned database. On this basis, the knowledge on the health impact of exposure to pollutants can be increased and recommendations for the safe management of chemicals will be derived to protect human health in Europe. One essential task of the initiative is the interaction with policy makers to ensure that the results are exploited in the design of new chemicals policies and the evaluation of existing measures.

The initiative's work includes several prioritisation rounds of substances of special interest. Phthalates were selected within the first prioritisation round due to the high concern among project partners as well as EU and national policy makers. Time trends and spatial trends in exposure of the European population to phthalates and the other prioritised substances will be assessed in existing HBM data from different countries as well as in European wide HBM data jointly collected within the initiative.

Chemical regulation will benefit largely from the initiative as based on the analysis of European HBM data, the impact of current regulation of phthalates will be evaluated. Results will be feed back into the regulation process.