

Announcement by the German Federal Environment Agency (Umweltbundesamt)

Derivation of human biomonitoring (HBM) values based on tolerable intake doses.

Part I: Introduction

Opinion of the Human Biomonitoring Commission of the German Federal Environment Agency (Umweltbundesamt)

The Human Biomonitoring Commission was established in 1992 at Germany's Federal Environment Agency. The Commission started its work with a series of basic papers on the scope and limits of human biomonitoring (HBM) and the attendant quality assurance issues. Then criteria for the derivation of reference and human biomonitoring values were published [1, 2]. The *reference value* is a statistically defined value that describes the exposure to or body burden of environmental contaminants of the (general) population. In contrast, HBM values are toxicology-based. Their derivation starts from scientific studies showing a correlation between the concentration in body matrices of a specific substance or its metabolites and adverse health effects. In this context, the *HBM I value* describes the concentration in a body matrix of a substance, below which, according to the Commission's current assessments, no impairment of health must be expected. Thus no remedial measures are deemed necessary. The *HBM II value* describes the concentration in a body matrix of a substance above which relevant adverse health effects may occur [3].

The Commission has so far published some 50 comments. It derived reference values for 23 substances and HBM values for four substances [4]. The relatively low number of HBM values is attributable to the lack of studies in humans on relevant biological effects which precludes the derivation of HBM values on the basis of the defined criteria [1, 2]. However, a toxicological assessment is necessary if human biomonitoring studies show a clear exposure of the general population to a certain

substance. A well established analytical method for the respective substance, its adducts or metabolites applicable for a readily accessible human biological matrix is a prerequisite for practicability.

In this context, the Commission has decided to derive HBM I values for substances for which a toxicokinetic extrapolation is possible which provides a concentration of a substance or its metabolites corresponding to tolerable intake doses derived by broadly accepted expert groups or organisations (like the acceptable daily intake (ADI) or the tolerable daily intake (TDI)). Another prerequisite for this way of derivation is the availability of basic toxicokinetic human data.

Being well aware of the uncertainties of such derivations and estimates, the Commission considers this new approach a possibility to derive urgently needed HBM values for substances or their metabolites for which no appropriate studies on health effects of low dose environmental exposure are currently available.

This approach supplements the way of deriving HBM values used up to now. It will be described in more detail in part II [5] and applied for the first time on di(2-ethylhexyl)phthalate (DEHP) in part III [6] of the present report, explicitly relating to a recent Commission monograph on this substance [7].

References

- [1] Kommission Human-Biomonitoring (1996a) Human-Biomonitoring: Definitionen, Möglichkeiten und Voraussetzungen. Bundesgesundheitsblatt 39: 213-215.
- [2] Kommission Human-Biomonitoring (1996b) Qualitätssicherung beim Human-Biomonitoring. Bundesgesundheitsblatt 39: 216-221.
- [3] Kommission Human-Biomonitoring (1996c) Konzept der Referenz- und Human-Biomonitoring-(HBM)-Werte in der Umweltmedizin. Bundesgesundheitsblatt 39: 221-224.
- [4] <http://www.umweltbundesamt.de/gesundheit-e/monitor/index.htm>
- [5] Kommission Human-Biomonitoring (2006) Ableitung von Human-Biomonitoring-(HBM)-Werten auf der Basis tolerabler Aufnahmemengen - Teil II: Grundlagen und Ableitungsweg. Bundesgesundheitsbl – Gesundheitsforsch – Gesundheitsschutz 50 (2): 251-254. (Derivation of human biomonitoring (HBM) values based on tolerable intake doses. Part II: Rationale and way of derivation; see: <http://www.umweltbundesamt.de/gesundheit-e/publikationen/index.htm#khhb>)

- [6] Kommission Human-Biomonitoring (2006) Ableitung von Human-Biomonitoring-(HBM)-Werten auf der Basis tolerabler Aufnahmemengen - Teil III: HBM-Werte für Di(2-ethylhexyl)phthalat (DEHP). Bundesgesundheitsbl – Gesundheitsforsch – Gesundheitsschutz 50 (2): 255-259 (Derivation of human biomonitoring (HBM) values based on tolerable intake doses. Part III: HBM values for di(2-ethylhexyl)phthalate (DEHP); see: <http://www.umweltbundesamt.de/gesundheits-e/publikationen/index.htm#khh>)
- [7] Kommission Human-Biomonitoring (2005) Stoffmonographie Di(2-ethylhexyl)phthalat (DEHP) – Referenzwerte für 5oxo-MEHP und 5OH-MEHP im Urin. Bundesgesundheitsbl – Gesundheitsforsch – Gesundheitsschutz 48 (6): 706-722. (Substance Monograph: Di(2-ethylhexyl)phthalate (DEHP) – Reference values for 5oxo-MEHP and 5OH-MEHP in urine; see: <http://www.umweltbundesamt.de/gesundheits-e/publikationen/index.htm#khh>)