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Announcement of the German Environment Agency (UBA)

HBM I values for Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) in blood plasma

Statement of the German Human Biomonitoring Commission (HBM Commission)

Based on an assessment of the literature on human epidemiological and animal studies which it discussed during its last meeting in may 2016, and following clarification of a few open details, the HBM Commission has decided to set HBM I values for PFOA and PFOS in blood plasma at 2 ng PFOA/ml and 5 ng PFOS/ml.

Rationale:

The HBM I value represents the concentration of a substance in a body matrix at and below which, according to the HBM Commission's current assessment, adverse health effects are not expected and therefore, no exposure reduction measures are necessary [1].

According to the policy paper on the derivation of HBM values by the HBM Commission [1], different methods can be used for derivation. The method chosen here was derivation on the basis of human data and critical effects.

Following evaluation of human epidemiological studies (status: July 2015/May 2016), the HBM Commission rates effects in the following areas as well proven, relevant, and significantly associated with exposure to PFOA and/or PFOS:

1. Fertility and pregnancy
   - Time to wanted pregnancy
   - Waiting period for pregnancies > 1 year
   - Gestosis and gestational diabetes
2. Weight of newborns at birth
3. Lipid metabolism
4. Immunity after vaccination, immunological development
5 Hormonal development, age at puberty/menarche
6. Thyroid metabolism
7. Onset of menopause

Based on the assessment of current literature, PODs (points of departure) were derived for the above effects. The literature reports different quantile contrasts, BMD (benchmark dose) derivations or regression analyses for continuous endpoints (e. g. birth weights, fat metabolism, sex hormones). Regarding quantile contrasts, the HBM Commission has chosen the upper bounds of the quantiles without significant effects (with a monotonic relationship). This is in line with the approach of the HBM I value, marking a level of protection at which "adverse health effects are not expected". BMD modelling usually leads to lower PODs, but cannot be carried out consistently with the available data.

The HBM Commission points out that the sample sizes and concentration ranges reported in different studies, and the chosen quantiles and confounders cannot be evaluated using a standard procedure.

The HBM Commission has therefore decided to use the resulting POD ranges as a basis for deriving the HBM I value. The expert opinion which it has on hand suggests a possible POD in the range of 1 to 10 ng/ml blood plasma for PFOA and of 1 to 15 ng/ml blood plasma for PFOS. Within these value ranges, the HBM Commission has set the HBM I value at 2 ng PFOA/ml blood plasma and 5 ng PFOS/ml blood plasma.

The consistency of results from animal and epidemiological studies was taken into account in the derivation.

Animal studies support the above line of reasoning in two respects:

1. Analogies between animal and epidemiological studies enhance the plausibility that the effects chosen as endpoints are relevant (e. g. humoral immunity, birth weight, (puberty) development)
2. Recent animal studies have also found effects in the low-dose range.

The pathomechanisms involved currently do not seem to be sufficiently clarified to provide a logical explanation of the effects observed.

The data available do not appear to show proof of a genotoxicity of PFOA and PFOS.

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References

1. Kommission HBM (2014) Grundsatzpapier zur Ableitung von HBM-Werten. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 57(1):138–147

This article is a translation of „HBM-I-Werte für Perfluoroctansäure (PFOA) und Perfluoroctansulfonsäure (PFOS) in Blutplasma. Stellungnahme der Kommission Human-Biomonitoring des Umweltbundesamtes" (DOI 10.1007/s00103-016-2434-4) published in this issue.