



HBM4EU

science and policy
for a healthy future

HORIZON2020 Programme
Contract No. 733032 HBM4EU

“Public consultation on behalf of the Commission: Update of Annex XIV entries of four phthalates”

- Comments from HBM4EU -

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1 Comments on the update of Annex XIV

1.1 Comments on transitional arrangements

Comments on the proposed Latest Application Dates and Sunset Dates

As representative of HBM4EU we argue for the earliest date possible for both, the Latest Application Date and Sunset Date.

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. 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.

1.2 Comments on uses exempted from the authorisation requirement

Comments on uses (or categories of uses) that should be exempted, including reasons for that

In our view as representative of HBM4EU, there should be no exemptions from the authorisation requirement. We think exemptions are not advisable, because (i) compounds with SVHC properties should not be released into the environment due to precautionary principle, (ii) there is evidence for anti-androgenic mixture effects (dose addition) of phthalates and (iii) imported goods are already exempted from authorisation. The proof of internal exposure in humans by human biomonitoring data underlines the need for stricter limitations of potential exposure sources.

1.3 Comments on review periods

Comments on uses for which review periods should be included in Annex XIV, including reasons for that

None

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.