

1 Prioritised substance group: UV filters-UPDATED

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1.1 Policy-related questions

1. Are sensitive, reliable and cost effective methods and biomarkers available to measure UV filters?
2. What are current exposure levels to benzophenones in the EU population (cumulative exposure from different exposures sources)?
3. What are the major sources of exposure to benzophenones in the EU population and in vulnerable groups such as children and pregnant women? (cosmetics and personal care products, plastic and other food contact materials, other)
4. Do exposure levels differ significantly between different EU countries (possibly related to climate)?
5. Do exposure levels differ between different sub-groups: elderly, adults, and children? Between males and females? Between adults of different age groups? Between individuals in different ethnic subgroups (perhaps due to differences in use of sunscreen products)?
6. Are current exposure levels safe in relation to the endocrine and carcinogenic properties of benzophenones? (for the general population and for vulnerable groups such as children and pregnant women)
7. Was the restriction of BP-3 in cosmetics in the EU (September 2017) effective in reducing public exposure? Did exposure to other benzophenone or other UV filter compounds increase as a result?

1.2 Research Activities to be undertaken

Table 1: Listing of research activities to be carried out to answer the policy questions

Table 2 Research activities research activities to be carried out to answer the policy questions for UV filters

Policy question	Substance	Available knowledge	Knowledge gaps and activities needed
1. Are sensitive, reliable and cost effective methods and biomarkers available to measure UV filters?	Benzophenones	Methods have been reported for BP-3 and three oxidative metabolites (2,4-dihydroxylbenzophenone, 2,2'-dihydroxy-4-methoxybenzophenone, and 2,3,4-trihydroxybenzophenone); and simultaneous measurement of 9 UV filters in urine	WP9 - Are HBM methods to measure BP-3 / its metabolites and other benzophenones quality assured? Are levels of detection and quantification adequate? - Is there a need to develop new analytical methods?
2. What are current level of exposure of the EU population to benzophenone UV-filters?	Benzophenones, emphasis on BP-3	Benzophenones are likely to be increasingly detected in the general population in the EU, due to their extensive use in personal care products (sunscreens), food contact materials, and other products.	WP7 & WP8; WP16 Systematic collection of available HBM data on benzophenones; Generation of data in targeted studies and from bio-banked samples if available. WP10 Is existing exposure data sufficient to derive valid estimates for the exposure of the EU population? What data is needed to derive reference values?
3. Do the exposure levels differ significantly between the countries?	Benzophenones, emphasis on BP-3	Human Biomonitoring data is scarce (only available for some countries with different population groups measured, e.g. France, Denmark)	WP7 & WP8; WP10; WP16 Systematic collection of available HBM data on benzophenones; Generation of data in targeted studies and from bio-banked samples if available.
4. What are the main sources of exposure to benzophenones?	Benzophenones	The main sources of exposure to benzophenones are cosmetics and personal care products; food packaging materials; and other uses in consumer products	WP10 What are major sources of exposure to benzophenones in the general population and in sub-groups? (per single substance and substance group) WP12 Estimation of the contribution of different routes of exposure to the total exposure.
5. Who are the highest exposed groups? Are there statistical differences in concentration between different ages? Males and females? Ethnic subgroups? Occupational vs. general population exposure.	Benzophenones, emphasis on BP-3	There is insufficient research to date to answer these questions; indications that exposure is higher in females due to increased use of personal care products and/ or cosmetics	WP10 - Based on existing data, determine different exposure levels between: males/females, different age groups (depending on the data available) - In case occupational population data exists, determine different exposure levels in occupational populations in comparison with the general population WP8 Targeted HBM studies on benzophenone exposure
6. How effective was the restriction of BP-3 in reducing exposures in the EU population?	BP-3 and other benzophenones	Since September 2017 the use of BP-3 has in EU been restricted to 6% in cosmetic sunscreen products and up to 0.5 % in other cosmetic products	WP10 - Compare between exposure to regulated UV-filters (BP-3) and nonregulated UV-filters

Policy question	Substance	Available knowledge	Knowledge gaps and activities needed
7. Are current exposure levels safe?	BP-3	The current research is not sufficient to answer this question	<p>WP5 Inclusion of HBM data in RA and HIA strategies Derivation of health based GV value</p> <p>WP10 E WP13 Investigate associations between exposure and health outcomes</p>
8	B	T	Assessing the feasibility of deriving an HBM health-based guidance value
9. How can HBM4EU results feed into regulatory decisions and risk assessments (ECHA and EFSA)?	UV filters, specifically BP-3		<p>WP5 - Derivation of Health-based guidance values using HBM data for benzophenones</p> <p>WP5 How can HBM data on benzophenones inform chemical risk assessment and management (exposure assessment, TDI evaluation)? What HBM data is needed to inform risk assessment and management?</p> <p>WP12,13,14 Instruments to link health and exposure and to better estimate risks will be explored and their suitability in risk assessment and management will be evaluated (e.g. cumulative risk assessment)</p>