

Breast Cancer UK response to the Consultation on the Opinion of the Committee for Risk Assessment and the Committee for Socio-Economic Analysis on an Annex XV dossier proposing restrictions on four phthalates (DEHP, BBP, DBP and DBIP)

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Breast Cancer UK is dedicated to the prevention of breast cancers by reducing public exposure to the carcinogenic, hazardous and hormone disrupting chemicals which are routinely found in the environment and everyday products.

Breast Cancer UK welcomes the restrictions placed on the four phthalates, bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), and benzyl butyl phthalate (BBP), in articles that cause exposure through being mouthed, through the skin, or by inhalation. However, we disagree with several of the derogations that are proposed (see below).

Our concerns relate to the potential role of the four phthalates DEHP, BBP, DBP and DBIP in harming human health, as outlined in the annex XV dossier, and to their potential role in increasing breast cancer risk. All four phthalates have been classified as endocrine disrupting chemicals (EDCs) due to their anti-androgenic properties. The dossier describes numerous detrimental health effects, mostly associated with male reproduction and development. It also includes potential effects on female reproduction and mammary gland development (which may affect breast cancer risk), and immune system, metabolic and neurological effects. Furthermore, recent *in vitro* studies demonstrate that at very low concentrations, BBP, DBP, and DEHP show oestrogenic activity, increase breast cell proliferation and prevent apoptosis (cell death), suggesting low, environmentally relevant concentrations of these phthalates may increase breast cancer risk (1). There is also evidence that low concentrations of BBP and DBP promote tumour growth of oestrogen receptor negative breast cancer cells through activation of the aryl hydrocarbon receptor (2), thereby increasing breast cancer risk through mechanisms independent of oestrogenic activity. BBP has been shown *in vitro* to reduce the effectiveness of breast cancer chemotherapy (3).

For these reasons, Breast Cancer UK welcomes the committees' conclusion that action should be taken on the restriction of the four phthalates used in articles however we do not agree there should be derogations for products used outdoors (provided articles do not come into prolonged contact with human skin or membranes), or in industrial or agricultural workplaces (provided they do not come into prolonged contact with human skin); or for measuring devices for laboratory use.

Such products will continue to contribute to emissions. All four phthalates are now classified as Substances of Very High Concern (SVHC) due to their classification as toxic for reproduction in category B and as EDCs for human health. In addition, DEHP has been classified as an EDC due to its effects on the environment. Phthalates are widespread in the environment, including air,

water, soil, sediment and biota and their metabolites are detected regularly in human body fluids (4). In addition, DEHP DIBP and DEP metabolites have been detected in breast milk (5). This is especially relevant as early exposures to endocrine disrupting chemicals are likely to be of greatest significance and are most hazardous to health. We therefore object to the presence of these phthalates in articles suitable for outdoor use, as these will continue to contribute to pollution of the outdoor environment.

We are disappointed that the proposed restrictions derogate food contact materials, but appreciate this is considered through separate regulations.

References

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