

Denmark prepared a restriction report on

FOUR CLASSIFIED PHTHALATES (DEHP, BBP, DBP AND DIBP)

SUMMARY

Denmark prepared a report proposing a restriction on the placing on the market and use of certain articles containing four classified phthalates (DEHP, BBP, DBP and DIBP). These phthalates are primarily found in PVC as softeners but they can also be found in low concentrations in other plastics and in e.g. dispersions, paints and varnishes.

These phthalates are all reported to affect reproductivity. The widespread use of these phthalates is causing concern to be raised regarding human exposure from consumer articles. The dossier addresses the combined exposure of the four phthalates based on the common effects seen from exposure to these phthalates.

The public consultation on the restriction report concludes on 16 March 2012. ECHA encourages interested parties to comment by 16 December 2011.

SUGGESTED RESTRICTION

Denmark has prepared a report (a so called Annex XV report) proposing to restrict four phthalates DEHP, BBP, DBP and DIBP. In the report, Denmark suggests a ban *for the placing on the market of articles intended for use indoors and articles that may come into direct contact with the skin or mucous membranes containing one or more of these four phthalates in a concentration greater than 0.1 % by weight of any plasticised material*. In this context, the definition of the term “use” means any placing, keeping, storing, hanging, laying, applying, mounting, fixing or other application indoors of articles. Furthermore, the report suggests derogations in order to account for the existing legislation, and a transitional period in the adoption of the ban.

The report contains a non-exhaustive exemplary list of articles that are covered and of articles that are not covered by the proposal. These are given in Annex 1.

USE OF PHTHALATES

The main use (94 %) of the four phthalates proposed for restriction is in PVC. Minor uses are in non-PVC polymers and non-polymers. The four phthalates can be found in a great variety of articles from floor coverings to sandals.

The report indicates that the EU annual production together with imports in 2009 - 2010 comprised about 230,000 tonnes per year, of which 210,000 tonnes is DEHP. The total use of the four phthalates in the EU for the production of articles was estimated to be 184,000 tonnes (2009). Furthermore, the total content of the four phthalates in the articles placed on the market in the EU that were proposed to be restricted is estimated to be 170,000 tonnes annually in 2009-2010 (a reduction of 36 % since 2007).

REASONS FOR ACTION

The phthalates DEHP, DBP, BBP and DIBP were reported to affect testicular functions and to have adverse effects on sexual differentiation during the developmental process. They were furthermore found to exert anti-androgenic effects. These toxicological effects have raised concerns regarding their endocrine-disrupting properties in terms of reproductive and developmental disorders in humans.

Due to the widespread use in a variety of applications, a concern is raised regarding human exposure to phthalates in articles. Individuals can be exposed to phthalates through inhalation (indoor air), ingestion (via food, toddlers suckling on plastic materials etc.), and mucous membranes and dermal contact.

The severity and extent of the possible health risks resulting from the combined exposure to the four phthalates, as well as the need to avoid market distortions creates a need to act on a Community-wide basis.

CONSEQUENCES OF THE ACTION

According to the report, the proposed restriction will result in a significantly decreased exposure of the public to the four phthalates caused by the use of articles containing these substances. DEHP, DBP and BBP are in the list of substances subject to authorisation (Annex XIV) of the REACH Regulation. DIBP is included in ECHA's second recommendation of substances to be included in that list. The authorisation requirement concerns the placing on the market and use of substances on their own or in mixtures, but it does not cover the use of articles containing these substances. The report also reflects on future effects of the authorisation requirement.

According to the report, alternatives exist allowing a quick phase-out. No information has been received that substitution of the four phthalates would imply major implementation problems. According to the report, the proposed restriction is also considered to be proportional and enforceable. Related to monitoring and enforcement, the testing cost is thought to be relevant especially for enforcement authorities. The importer, retailers etc would normally rely on the information from suppliers on the content according to the report.

COMMENTS PREFERABLY BY 16 DECEMBER

The opinion forming process of the ECHA Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) starts with a public consultation on 16 September 2011. Interested parties can comment on the proposal and the restriction report on the ECHA website. Although the public consultation concludes on 16 March 2012, the rapporteurs of RAC and SEAC would appreciate receiving comments by 16 December 2011 to assist them in the detailed discussion of the restriction proposal in January 2012.

The final opinions of both Committees are scheduled to be available by 16 September 2012. ECHA will send these two opinions to the European Commission, which will take the decision whether to include new restrictions in Annex XVII of the REACH Regulation.

[Submit comments on the restriction report](#)
[Link to the restriction report](#)
[Link to the news alert](#)
[More information on Restriction process](#)

Annex 1:

A non-exhaustive exemplary list of articles to be covered by the proposal:

- childcare articles (for DIBP);
- interiors of cars, trains, ships, boats, aircrafts etc.;
- wall covering and flooring;
- insulation on wires used indoors;
- insulation on cables used indoors in unsealed applications;
- electric and electronic equipment;
- coated fabric and film/sheets used for furniture;
- coated fabric and film/sheets used for bags and briefcases/suitcases and similar items;
- coated fabrics and film/sheets used for tablecloth, curtains, shower curtains and similar items;
- carpet tiles/squares produced with foam as back cover;
- water mattresses and air mattresses;
- wallpaper/tapestry;
- footwear;
- textiles;
- bathing equipment (swim jackets, wings, belts and pools - inflatable and others);
- erasers;
- balance balls for playing (not toys) and physical exercises;
- sex toys;
- garden hoses, and
- garden tools which have phthalates contained in handles.

A non-exhaustive exemplary list of articles not to be covered by the proposal:

- insulation on wires and cables used outdoors;
- large-scale stationary industrial tools;
- roofing material;
- car undercoating, and
- garden tools which only have phthalates contained in parts other than handles.