

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

LAY SUMMARY STATEMENT ON RESTRICTION REPORT: PROPOSAL FOR A RESTRICTION - BIS(2-ETHYLHEXYL)PHTHALATE (DEHP), BENZYL BUTYL PHTHALATE (BBP), DIBUTYL PHTHALATE (DBP) AND DIISOBUTYL PHTHALATE (DiBP).

Introduction

1. Phthalates (phthalic acid esters) are chemical compounds made from phthalic acid. They are used as plasticisers (softening agents) in PVC and other plastics, and have various industrial applications, including the manufacture of household and consumer goods such as vinyl floorings, wallpaper, furniture, paints, varnishes, cosmetics, perfumes, lubricating oils, solvents, and food packaging. They may occur as trace contaminants in food because of their widespread presence as environmental contaminants and through their release from plastic food packaging
2. Phthalates can interact with the hormonal (endocrine) control systems of the body, and in particular those that regulate reproductive function.
3. In the EU, there is legislation to ensure that materials which come into contact with food (directly or indirectly) do not transfer phthalates to food in quantities large enough to endanger human health.
4. The Danish Environmental Protection Agency (EPA), which is the Danish Competent Authority for REACH (Registration Authorisation and restriction of Chemicals) within the European Union (EU), recently drafted a proposal to restrict further the marketing of articles and products containing four of the phthalate esters, namely DEHP, BBP, DBP and DiBP*.
5. The Committee on Toxicity (COT) was asked by the Health and Safety Executive (HSE) to advise on the risk assessment carried out by the Danish EPA.
6. The COT had previously considered the toxicology of a number of phthalate esters, and in May 2011 had published a statement on dietary exposure to phthalates, based on data from a Food Standards Agency (FSA) total diet study (TDS).

<http://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2011/cot201104>

* Bis(2-ethylhexyl)phthalate (DEHP), Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DiBP).

Overview of Danish EPA Restriction Report

7. In their “Restriction Report”, the Danish EPA estimated potential exposures to each of the four phthalate esters of concern, from a wide range of sources, including various household articles and products, dust in indoor air, and food. Estimates of the total exposures which might plausibly occur, were then compared to “Derived No Effect Levels (DNELs)” for the chemicals. A DNEL is a maximum level of daily exposure at which there is reasonable confidence, based on available toxicological evidence, that adverse effects on health would not occur. The authors proposed that the combined toxicity of the four phthalate esters under review could be characterised by calculations assuming “dose addition”. This allowed assessment of overall risks from exposure to all four substances.

8. The Danish EPA concluded that there was sufficient uncertainty about the safety of potential exposures to justify further regulatory restrictions on the four phthalates. Thus, they proposed that within the EU it should not be permitted to place on the market articles intended for use indoors in unsealed applications, or that might come into direct contact with people’s skin or mucous membranes, if they contained one or more of DEHP, BBP, DBP and DiBP at a concentration greater than 0.1% by weight of any plasticised material.

COT consideration and conclusion

9. The COT noted that the assessment of risks from combined exposures to DEHP, DBP, BBP and DiBP that was set out in the Danish Restriction Report entailed a number of conservative assumptions. These related both to levels of exposure which might reasonably be expected to occur, and also to the toxicity of one of the chemicals under consideration (DBP). In view of this conservatism, and the calculated ratios of potential exposures to DNELs, which were not so high as to be of major immediate concern, the COT judged that the risk assessment did not necessarily indicate a need for risk reduction measures beyond those that are already in place.

10. An alternative would be to refine the risk assessment before deciding whether additional regulatory action was appropriate. To this end, it would be most useful to collect further biomonitoring data from representative samples of people, as a means of better characterising the distribution and determinants of total exposures to phthalates in different sections (e.g. age groups) of the general population. Furthermore, if concerns about safety remained after a more refined risk assessment, there would also be value in carrying out a more thorough risk assessment for other products which might be used as substitutes should additional restrictions be imposed on DEHP, DHP, BBP and DiBP.

11. The full COT statement can be found at:
<http://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2011/cot201106>