

15 March 2016

To the UK National Representatives on the REACH Committee meeting 16th/17th March 2016

I write on behalf of Breast Cancer UK, to draw your attention to two decisions due to take place at tomorrow's meeting of the REACH Committee in Brussels which have the potential to impact public exposures to harmful chemicals that have been linked in scientific studies to adverse health effects, amongst them, breast cancer.

We ask you to support the European Commission's proposal to identify four phthalates (DEHP, DBP, BBP and DIBP) as Substances of Very High Concern (according to Article 57(f) of REACH) and to reject the Commission's proposal to grant authorisation for the use of DEHP in consumer articles made with recycled PVC.

Support the identification of four phthalates (DEHP, DBP, BBP and DIBP) as endocrine disrupters (ED)

During the REACH Committee meeting, Member States will vote on whether the above four phthalates should be listed as EDCs due to their human health effects. As the Commission proposal notes, Member States have already unanimously agreed in the Member State Committee (MSC) that these four substances have endocrine disrupting properties for human health. Only, four Member States had objections to their identification as SVHC according to Article 57(f) due to the fact that they are already included in the Candidate List (and authorisation list) as substances that are toxic for reproduction (category 1B). However, as the Commission's proposal also notes, Article 57 does not preclude the ability to identify a substance as being of very high concern several times over. In fact, other chemicals are listed as carcinogenic and mutagenic, and this is not considered double counting.

We agree with the majority of Member States and the Commission on the importance of specifying the mode of action of these phthalates as endocrine disrupters by identifying them as SVHC according to Article 57(f), as this would better reflect existing scientific knowledge on these substances.

Listing DEHP, DBP, BBP and DIBP as EDCs for human health will lead to different risk management considerations in the REACH authorisation and restriction processes. For example, the REACH Review of how EDCs should be assessed noted that "it may be difficult (albeit not impossible) to determine a safe threshold with reasonable certainty for endocrine disruptors, taking into consideration all uncertainties related to EDs".

Although the deadline for submitting applications for authorisation for these substances has already expired, Denmark and ECHA will soon submit a restriction proposal for these four substances, in order to avoid the exposure of people and the environment through imported articles. The identification of the four phthalates as EDCs for human health is a crucial consideration in this upcoming restriction process because as EDC for human health any level of exposure would constitute a risk to be addressed.

Reject granting authorisation to the use of DEHP in recycled consumer articles.

Vinyloop Ferrara, Stena Recycling and Plastic Planet have applied for authorisation of the use of DEHP in recycled soft PVC containing articles. Granting authorisations for these applications would not be in keeping with the provisions of Title VII of REACH, in particular Articles 60, 62 and 64 of REACH and would undermine the main objective of REACH “to encourage and [...] to ensure that substances of high concern are eventually replaced by less hazardous substances or technologies where suitable economically and technically viable alternatives are available”.

The risks related to the uses of DEHP are not adequately controlled as RAC has clearly stated in its opinion.

There are suitable alternative substances and technologies. As highlighted in the SEAC's opinion, the applicants, when providing their analysis of alternatives, discarded alternative materials, substances and techniques claiming that they cannot produce the alternatives, even though authorisation is sought for many downstream uses, not for manufacturing. Furthermore, DEHP has, to a large extent, already been replaced by other plasticisers and materials. During the public consultation, manufacturers of alternatives as well as downstream users applying these alternatives have provided overwhelming information which shows that readily available and technically and economically feasible alternatives do exist.

The applicants could not demonstrate that the socio-economic benefits of continued use outweigh the risk to human health or the environment. SEACs opinion confirms that there were significant deficiencies in the socio-economic analysis presented by the applicant, including the lack of any health impact assessment identifying the remaining risk to workers' health. Therefore, the legal requirements of Article 60(2) and 60(4) are not met and the authorisation must not be granted.

DEHP has been linked to numerous adverse health effects, including breast cancer, in scientific studies. In animal studies, exposure to DEHP is associated with adverse effects on the liver, kidneys, blood and the reproductive system, leydig cell tumours and leukaemia. Several studies on humans have demonstrated effects on sperm quality, genital tract problems¹, endometriosis² and cancers, including breast cancer³. An *in vitro* study found that even at very low concentrations DEHP induces oestrogenic effects, including breast cancer cell proliferation⁴. Taken together, these findings suggest environmental levels of DEHP pose a significant public health risk including an increased risk of breast cancer.

We also would like to recall to your attention the EU Parliament's Resolution⁵ of 25 November 2015 calling on the Commission to reject the applications for authorisation for the formulation of recycled soft PVC containing DEHP.

You can find further details regarding the procedural and substantive flaws of the ECHA's Committees opinions DEHP in a letter sent to the Commission by 55 Civil Society Organisations⁶ and in the EEB's report “A Roadmap to revitalise REACH”⁷.

As you can see, the decisions that you will take during next Reach Committee will have a substantial impact in reducing the exposure of people, including vulnerable populations to well known toxic substances with

¹ Swan, S. H. et al. (2015). First trimester phthalate exposure and anogenital distance in newborns. *Human Reproduction* 30 (4) 963-972

² Upton, K. (2013). Phthalates and risk of endometriosis. *Environmental Research* 126 91–97.

³ Holmes A. K. et al. (2014). Case–control study of breast cancer and exposure to synthetic environmental chemicals among Alaska Native women. *International Journal of Circumpolar Health* 73: 257260.

⁴ Chen P. P. and Chien M.-H. (2014). Lower concentrations of phthalates induce proliferation in human breast cancer cells. *Climacteric* 17 (4) 377-338.

⁵<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P8-TA-2015-0409+0+DOC+PDF+V0//EN>

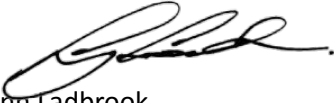
⁶<http://www.eeb.org/EEB/?LinkServID=D3B03D7A-5056-B741-DB6A261F59EEDAD6>

⁷<http://www.eeb.org/index.cfm/library/a-roadmap-to-revitalise-reach/>

evidenced links to adverse human health effects.

These decisions will also either reflect the spirit of the REACH law, or contradict its main purpose. We therefore call upon you to oppose the authorisation.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Lynn Ladbrook', with a small dot at the end.

Lynn Ladbrook
CEO
Breast Cancer UK