

Rory Stewart OBE MP
Department for Environment, Food and Rural Affairs
Nobel House
17 Smith Square
London
SW1P 3JR

17th September 2015

Dear Minister

REACH Committee meeting 22/23 September

I am writing on behalf of Breast Cancer UK to urge DEFRA representatives to oppose the applications for the authorization of the continued use of **Diethylhexyl phthalate (DEHP)**, **Hexabromocyclododecane (HBCDD)** and Lead chromate pigments, at the above meeting as the applications do not fulfill the requirements established by REACH for authorisation and each poses a significant risk to public health and the environment.

Diethylhexyl phthalate (DEHP)

The companies VINYLOOP FERRARA, Stena Recycling and Plastic Planet have applied for use of DEHP for the manufacturing of soft recycled PVC consumer articles, including flooring, upholstery, footwear and car seats, to which people, including young children, are routinely exposed. In our opinion, **the application for DEHP in recycled PVC does not fulfill the requirements established by REACH for authorisation for the following reasons:**

- The Risk Assessment Committee (RAC) consider that the health and safety risks posed by DEHP in the workplace are not adequately controlled;
- The applicants failed to demonstrate that no alternatives were available for all uses applied for;
- Extensive information provided through the public consultation demonstrated that safer alternatives are available for many downstream uses;
- The Committee for Socio-economic Analysis (SEAC) considered that there were significant deficiencies in the socio-economic analysis presented by the applicants, including a health impact assessment identifying the remaining risks to workers health.

Furthermore, DEHP is on the REACH candidate list as a substance of very high concern (SVHC); it is a reproductive toxicant and has endocrine-disrupting properties. IARC has classified DEHP as possibly carcinogenic for humans. In animal studies, exposure to DEHP is associated with adverse effects on the liver, kidneys, blood and the reproductive system, and cause leydig cell tumours and leukaemiaⁱ. Several human studies have suggested associations with poor sperm quality, genital tract problemsⁱⁱ, endometriosisⁱⁱⁱ and cancers, including breast cancer^{iv}. An *in vitro* study found that even at very low concentrations DEHP induces oestrogenic effects, including breast cancer cell proliferation^v. Taken together, these findings suggest environmental levels of DEHP pose a significant public health risk including an increased risk of breast cancer. DEHP is already restricted in toys and childcare articles under other EU regulations. However, children are still highly exposed to consumer products that contain DEHP, including textiles, footwear or car seats. Due to their rapid growth and incomplete metabolic system, fetuses and infants are especially vulnerable to the harmful effects of endocrine-disrupting chemicals

Hexabromocyclododecane (HBCDD)

Thirteen companies have applied for the continued use of HBCDD as a flame retardant for the manufacture of polystyrene insulation. **The application for continued use of HBCDD does not fulfill the requirements**

established by REACH Regulation for authorisation for the following reasons:

- The information provided in the HBCDD application did not conform to the legal text requirements, as emissions to the environment and those caused by downstream users were not adequately described.
- No worker exposure assessment was provided.
- The applicant did not demonstrate that the proposed risk management measures were appropriate and effective.
- Information provided through the public consultation demonstrated that technically and economically feasible alternatives are available in sufficient quantities.

Furthermore the granting of this authorisation would likely entail the further use of 32,000 tonnes of HBCDD within Europe and cause widespread contamination of the environment, as well as exposure to workers and the population. HBCDD was included in the candidate list due to its persistent, bioaccumulative and toxic (PBT) properties and has also been classified as a reprotoxicant that will be phased out globally by 2020, under the Stockholm Convention on Persistent Organic Pollutants. HBCDD is also an endocrine disruptor which mainly affects thyroid hormones and may be associated with thyroid disorders in humans^{vi}. Exposure of laboratory animals to environmentally relevant levels of HBCDD and polybrominated diphenyl ethers causes developmental abnormalities in offspring^{vii} including abnormal number of digits. *in utero* exposure in animals produces diverse developmental effects in the exposed offspring, including reduced bone density. HBCDD is also oestrogenic^{viii} *in vitro* which suggests it may increase risk of breast cancer in humans.

Lead chromates

The scope of the application to continue the authorisation of Lead chromate pigments is too broad, covering not only the manufacture of the pigments but also professional users and SMEs. Information on the number of downstream users and total number of exposed workers was not provided. Moreover, the socio-economic analysis provided by the applicant was not realistic. As a consequence, **the information provided in the application for lead chromates was not in conformity with the legal text requirements as important hazard and exposure data were missing.**

Moreover, Lead chromates are officially classified in the EU as carcinogens, toxic for reproduction and hazardous to the aquatic environment. Lead chromates were acknowledged to be substances of very high concern (SVHC) in 2010 and were included in the list of priority substances that should be phased out, namely the authorisation list in 2013. Because of the toxic effects of lead chromates, European paint manufacturers have banned lead pigments from all industrial coatings since 2011. Nevertheless, the EU Chemicals Agency (ECHA) is now recommending 12 years authorisation to a Canadian company based on a supposed lack of suitable alternatives. If a decision were to go ahead, it would mean that toxic chemicals not used in paints by EU manufacturers for four years may be allowed to return with the potential for them to end up in the European environment.

The REACH authorisation process aims to promote the substitution of substances of high concern with safer alternatives and there is much evidence to show that this is working. However, if the above authorisations are granted, it will seriously undermine this progress, threaten the principles upon which REACH is based and stifle innovation and greener chemistry, as well as posing a long term and irreversible threat to public health and the environment. For all these reasons, we ask you to oppose the granting of authorisation to these applications at next week's REACH Committee Meeting.

Yours sincerely,



Lynn Ladbrook
Chief Executive

Further information:

DEHP

Position paper: [55 EUROPEAN AND INTERNATIONAL CIVIL SOCIETY ORGANISATIONS ASK COMMISSION TO REJECT AUTHORISATION OF HAZARDOUS DEHP IN PVC PLASTIC](#)

Letter to the European Commission November 2014: [European and international civil society organisations ask Commission to reject authorisation of hazardous DEHP in PVC plastic](#)

Letter to the European Commission January 2015: [Procedural and substantive flaws of the DEHP in PVC opinions](#)

Letter to REACH Committee January 2015: [European civil society organisations ask Commission to reject authorisation of the substance of very high concern DEHP in PVC plastic](#)
[EEB Scorecard DEHP in PVC](#)

HBCDD

[EEB Scorecard HBCDD](#)

Lead chromates

[EEB press release lead chromates](#)

[EEB scorecard lead chromates](#)

ⁱ <http://www.nicnas.gov.au/communications/publications/information-sheets/existing-chemical-info-sheets/diethylhexyl-phthalate-dehp-factsheet>

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

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

^{iv} 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.

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

^{vi} Lyche et al. (2015). Human health risk associated with brominated flame-retardants (BFRs). *Environment International* 74: 170–180.

^{vii} Berger et al. (2014). Exposure to an environmentally relevant mixture of brominated flame retardants affects fetal development in Sprague-Dawley rats. *Toxicology*, 320: 56–66.

^{viii} Dorosh et al. (2011). Assessing Oestrogenic Effects of Brominated Flame Retardants Hexabromocyclododecane and Tetrabromobisphenol A on MCF-7 Cells. *Folia Biologica* 57: 35-39